Supreme Court, U.S.
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No. 03-388

IN THE
Supreme Court of the United States

DENNIS BATES, ET AL.,
Petitioners,
v.
DOW AGROSCIENCES LLC,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF FOR PETITIONERS

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QUESTION PRESENTED

Which, if any, state-law crop damage claims are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 *et seq.*

PARTIES TO THE PROCEEDING

Plaintiff-Appellee in the proceedings below was Dow AgroSciences LLC.

Defendants-Appellants in the proceedings below were Dennis Bates; Jimmy Burson; Benny Judah d/b/a Clearwater Farms; Tommy Coleman; Richard Cox; Wayne Davis; Neil Friessen; Jake Forese; Thomas Fuston; Arthur Galvan d/b/a G-5 Partnership; Greg Hughes; Sandra and Karl Don Hughes d/b/a JH Cattle Co.; Rudy Klassen; Ronnie Love; Kevin Mathis; Brad Palmer; Kirk Parrish d/b/a K-L Farms; Jerry Parrish; Joevelyn Patterson; Donald Gruben; Stacey Price; Benny Judah d/b/a Progressive Farms; Morris Rushing d/b/a Pea-Cot Farms; Billy Shannon; Floyd Stokes; Craig West; and Frenchie Lee Wheeler.

Burk Denman was a Defendant in the district court proceedings but was dismissed as an Appellant in the court of appeals proceedings.

STATEMENT PURSUANT TO RULE 29.6

None of the corporate Petitioners has a parent company, and no publicly held company owns 10% or more of the stock of any such corporate Petitioner.

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The district court's opinion (Pet. App. 21a-31a) is reported at 205 F. Supp. 2d 623. The court of appeals' opinion (Pet. App. 1a-20a) is reported at 332 F.3d 323.

JURISDICTION

The court of appeals entered judgment on June 11, 2003. The petition for a writ of certiorari was filed on September 9, 2003, and granted on June 28, 2004 (124 S. Ct. 2903). Jurisdiction rests on 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS

Relevant provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 *et seq.*, and of Title 40 of the Code of Federal Regulations are reproduced in an addendum to this brief.

STATEMENT

Petitioners are a group of Texas farmers who seek recovery under state law for the substantial crop damage caused by a pesticide, Strongarm, in the growing season immediately after the Environmental Protection Agency ("EPA") approved it. They asserted the same types of claims that have been made against pesticide manufacturers for nearly a century – strict liability in tort, breach of warranty, breach of contract, negligence, fraud, and deceptive trade practices. Those claims arose out of the respondent manufacturer's written representations on the pesticide's label, and oral representations made in face-to-face meetings with the farmers before and after they purchased and applied Strongarm to the soil. In holding all of those claims preempted, the court below gave sweeping effect to the preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v(b). The court opined that any state-law liability that might "induce" the manufacturer to change its label was "express[ly]" preempted under § 136v(b). Pet. App. 20a.

That holding affords pesticide manufacturers *carte blanche* to determine the scope of preemption because they – and not federal regulators – decide what to put on the

label. The notion that manufacturers have the authority to preempt claims that seek to redress injuries they cause, however, is alien to this Court's approach to preemption analysis, Congress's purposes in enacting FIFRA, historical practice throughout the twentieth century, and common sense. In legislation that sought to address the potential horrors of an unregulated pesticide industry, it is unthinkable that Congress – without debate – intended to exonerate manufacturers from traditional state-law remedies for the injuries they cause from dangerous chemicals.

1. Beginning in the late nineteenth century, farmers in the United States began to use a variety of primitive chemicals to attack insect pests, such as Paris green (a concoction of copper and arsenic), calcium arsenate, nicotine sulfate, and sulfur. *See* J. Whorton, *Before Silent Spring* 20-21 (1974). Those primitive chemicals augured significant changes in the agricultural pesticide industry, which grew dramatically after World War II, when advances in chemistry occasioned by military needs led to the introduction of DDT and BHC, among others. *See, e.g., id.* at 248-50; *Report of the Secretary's Commission on Pesticides and Their Relationship to Environmental Health* 44-46 (U.S. Dep't HEW 1969) ("*HEW Report*"). The seeming euphoria over the benefits of pesticides in general, and DDT in particular, led to a 1944 Nobel Prize award to the inventor of DDT. But by the 1960s, following publication in 1962 of Rachel Carson's *Silent Spring*, a major reassessment began of pesticides, due to the human health risks and environmental hazards caused by DDT. *See generally* H. Wellford, *Sowing the Wind* (1972); F. Graham, *Since Silent Spring* (1970); R. Rudd, *Pesticides and the Living Landscape* (1964). In 1972, EPA cancelled the registration of DDT in the United States. By 2001, 92 nations (including the U.S.) had signed a treaty pledging to phase out persistent organic pollutants, including DDT. *See* Stockholm Convention on Persistent Organic Pollutants, May 22, 2001, 40 I.L.M. 532, *at* http://www.pops.int/.

Notwithstanding the disastrous experience with DDT, pesticide use on farms rose rapidly in the 1960s, from $440 million in sales in 1964 to $12 billion in 1969. *HEW Report* at 46. Some 900 active pesticidal chemicals formulated into more than 60,000 preparations were marketed by that time. *Id.* By 1976, pesticides were used on 70% of U.S farm acreage planted, up from 50% five years before. *See* George Getschow, *Farmers Using More and More Pesticides To Safeguard Investment as Well as Crops*, Wall St. J., June 14, 1976, at 24.

2. The introduction of pesticides early in the twentieth century, and the attendant problems they created, led Congress to enact the Insecticide Act of 1910. That Act was principally a labeling measure covering insecticides and fungicides, the purpose being to prohibit the manufacture or shipment of misbranded or adulterated products that move in interstate commerce. *Id.* §§ 1, 2, 36 Stat. 331. Although the Department of Agriculture ("USDA") was authorized to examine specimens, Congress did not require registration or other government approval of pesticides. *Id.* § 4, 36 Stat. 332. The 1910 Act was silent as to civil remedies for violations, providing only for criminal penalties and civil actions by the federal government. *Id.* §§ 1-2, 10, 36 Stat. 331, 334.

In 1947, Congress enacted FIFRA, which repealed the 1910 Act, *see* § 16, 61 Stat. 172. FIFRA provided that an "economic poison" – otherwise defined as a chemical pesticide – had to be registered before being marketed in interstate commerce. *Id.* § 4(a), 61 Stat. 167. "Like its 1910 predecessor, the principal thrust of the 1947 FIFRA was to protect consumers on the farm and in the orchard from ineffective products." 3 W. Rodgers, Jr., *Environmental Law: Pesticides and Toxic Substances* § 5.3, at 34 (1988).

By the end of the 1960s, however, it was clear that the existing system of federal pesticide regulation was inadequate. A House subcommittee investigation in 1969 chronicled a plethora of problems, including approvals of pesticides without compliance with federal procedures,

approvals of labels that failed to warn users of possible hazards, and actions to cancel dangerous pesticides that were substantially delayed. *See* H.R. Rep. No. 91-637 (1969); *see also* Rodgers § 5.2, at 31.

Notwithstanding enactment of the 1910 or 1947 Acts, including the requirement that pesticides be federally registered before entering interstate commerce, from the earliest uses of agricultural chemicals, farmers commonly pursued claims for compensation under common law and state statutes for injuries caused by pesticides. For example, claims against pesticide manufacturers alleged crop damage for failure to test a product before it was released into the market.[1] Indeed, state courts imposed on manufacturers a duty to test their products for safety and effectiveness "under the existing climactic and soil conditions" of each State in which they sold the product. *Ebers v. General Chem. Co.*, 17 N.W.2d 176, 181 (Mich. 1945) ("[D]efendant cannot escape liability merely by showing that it followed the recommendations of [USDA] . . . based upon field tests in States *other* than Michigan.") (emphasis added). Likewise, courts upheld farmers' crop damage claims sounding in negligence under a duty to warn theory.[2] And courts routinely recognized claims against pesticide manufacturers for personal injuries.[3]

[1] *See, e.g., Chapman Chem. Co. v. Taylor*, 222 S.W.2d 820, 827 (Ark. 1949) (manufacturer "charged with the knowledge which tests would have revealed"); *Henderson v. Cominco Am., Inc.*, 518 P.2d 873, 879, 882-83 (Idaho 1973) (recognizing claim for "failing to test the product").

[2] *See, e.g., Golden Gate Hop Ranch, Inc. v. Velsicol Chem. Corp.*, 403 P.2d 351, 355 (Wash. 1965) ("[I]f [the manufacturer] knew or should have known that the product was dangerous to hops, the appellant was negligent in not advising the respondent of the danger."); *Thompson-Hayward Chem. Co. v. Childress*, 169 So. 2d 305, 312 (Ala. 1964) (recognizing claim for "failure to give notice to or warn plaintiffs of the dangerous nature of [a herbicide]"); *Reasor-Hill Corp. v. Kennedy*, 272 S.W.2d 685, 691 (Ark. 1954) (affirming verdict for failure to warn against crop damage due to insecticide drift).

[3] *Hubbard-Hall Chem. Co. v. Silverman*, 340 F.2d 402, 404 (1st Cir. 1965) (upholding verdict on failure-to-warn claims for personal injury;

By the 1960s, the "principles of law which are deducible" from the scores of cases decided throughout the twentieth century involving claims against pesticide manufacturers and sellers led to this statement of settled law: "A duty of due, reasonable care binds [pesticide] manufacturers . . . . This duty of care includes a duty to warn of product-connected dangers, a duty on the part of the manufacturer to subject the product to reasonable tests, and a duty on the part of the seller to subject the product to reasonable inspection." R.D. Hursh, *Liability of manufacturer or seller for injury caused by animal feed or medicines, crop sprays, fertilizers, insecticides, rodenticides, and similar products*, 81 A.L.R.2d 138, 144 (1962) (footnotes omitted).

3. Congressional enactment of the Federal Environmental Pesticide Control Act of 1972 ("1972 Act") amended FIFRA in important ways. *See* § 2, 86 Stat. 973-98, codified at 7 U.S.C. §§ 136 *et seq.*[4] The 1972 Act contained a more detailed registration provision (§ 136a(c) (1976)); added criteria for approval (§ 136a(c)(5)); and imposed consequences of disapproval (§ 136a(c)(6)). 86 Stat. 979-81. Congress augmented the 1970 transfer of authority to administer pesticide registration from USDA to EPA by providing in the 1972 Act for federal authority over the sale and use of pesticides. *E.g.*, § 136j. But the Act also expressly ensured that state and local governments had broad authority to regulate or even ban the sale and use of a federally registered pesticide. § 136v(a). States have the lead in enforcing pesticide use restrictions. § 136w-1.

finding no FIFRA preemption from label registration, but noting that defendants' compliance with FIFRA labeling requirements was "some evidence that . . . they exercised reasonable care"); *Orr v. Shell Oil Co.*, 177 S.W.2d 608, 614 (Mo. 1943) (affirming verdict against insecticide manufacturer for negligently failing to warn of dangers of human contact with spray ingredients); *West Disinfecting Co. v. Plummer*, 44 App. D.C. 345, 355 (1916) (affirming damages verdict for plaintiff for burn injuries where insecticide manufacturer breached its "duty . . . to label the can containing the fluid so as to show its dangerous character").

[4] Subsequent statutory cites are to Title 7 unless otherwise noted.

As part of the registration process, the manufacturer submits health and environmental data, as well as a draft label. § 136a(c)(1)(C); 40 C.F.R. § 152.50(e). EPA has stressed that "[t]he registrant must take responsibility for quality control of the product's composition and for adequate labeling describing the product, its hazards and uses." 53 Fed. Reg. 15,952, 15,956 (1988). Unlike federal statutes governing tobacco labels, *see* 15 U.S.C. §§ 1333, 4402(a)(1), neither FIFRA nor EPA regulations dictate that any particular language must be used for pesticide labels, except with respect to certain required "signal words" designed to protect human health if the pesticide contains ingredients in three of four toxicity categories. *See* 40 C.F.R. §§ 156.60-156.78.

If a manufacturer meets FIFRA's requirements, then EPA is obliged to register the pesticide. § 136a(c)(5), (7); 40 C.F.R. §§ 152.112, 152.113. Those requirements include: "the name and address of the applicant"; "the name of the pesticide"; "a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use"; "the complete formula of the pesticide"; a request as to the product's use (*i.e.*, general or restricted); and, "if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based." § 136a(c)(1)(A)-(F). A "label" is defined as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers," or other detached written matter accompanying the pesticide, such as an instructional booklet, that serves the same purpose as a label. § 136(p)(1), (2)(A). Information required by FIFRA to be on a pesticide's label must be prominently and conspicuously placed in comparison to other labeling information that is not mandated by federal law. § 136(q)(1)(E); 40 C.F.R. § 156.10(a)(2).

Notwithstanding EPA's registration of a pesticide, a label is "misbranded" if it bears false or misleading statements, contains improper directions for use, or displays inadequate cautions or warnings. § 136(q)(1)(A), (F), (G);

see also § 136a(c)(5). Cognizant that, "[f]or liability reasons, companies often voluntarily provide additional information on the label, particularly in the area of precautionary statements," 49 Fed. Reg. 37,960, 37,971 (1984), FIFRA and EPA permit such statements if they do not violate a specific statutory or regulatory requirement, *id.*

4. Although the 1972 Act required EPA to consider data and manufacturer claims concerning the efficacy of a pesticide in determining whether "its composition is such as to warrant the proposed claims for it," § 136a(c)(5)(A) (1976), those burdens were simply too great for the agency. In 1977, EPA Administrator Douglas M. Costle testified, "we feel that far too much Agency time is currently being spent in reviewing efficacy data while shortages abound in the reregistration data validation areas. Since the registrant, the USDA, and pesticide users are generally in a better position to judge efficacy, particularly of agricultural pesticides, we are proposing that the Agency should have explicit authority to waive the efficacy data requirement when appropriate." H.R. Rep. No. 95-343, at 9 (1977). In 1978, Congress acceded to that request by amending the 1972 Act to allow the EPA to waive data requirements "pertaining to efficacy" and to establish a "presumption" in favor of waiver if a pesticide is found to be effective by a state. Federal Pesticide Act of 1978, Pub. L. No. 95-396, § 5, 92 Stat. 819, 825 (§ 136a(c)(5)). EPA then issued a general waiver of its review of label claims concerning pesticide efficacy. *See, e.g.*, 44 Fed. Reg. 27,932 (1979). "The assumption in 1978 was that market choices and user votes of confidence were a fair barometer of product workability." Rodgers § 5.3, at 51.

That assumption was confirmed explicitly in 1996, when EPA issued Pesticide Registration Notice 96-4. That notice stated that "it would be incorrect to contend that the label approval process involves an examination of the efficacy of the pesticide." JA 232. EPA noted that the agency, "with Congress' approval, stopped evaluating pesticide efficacy for routine label approvals almost two decades ago.

Further, . . . EPA's regulations do not require a review of efficacy of property damage issues for agricultural pesticides." *Id.* EPA further clarified that the statutory prohibition on "misbranding" "should not be read as reintroducing efficacy concerns into the label approval process." JA 233-34. EPA concluded by stating, "as to pesticide users this Notice is intended to clarify that EPA's approval of a pesticide label does not reflect any determination on the part of EPA that the pesticide will be efficacious or will not damage crops or cause other property damage." JA 235. That guidance – and EPA's 1979 waiver – were in effect when Strongarm was registered.

5. In the early 1990s, the corporate predecessor to respondent Dow AgroSciences LLC ("Dow") began testing and developing a new herbicide that became known as Strongarm.[5] This product was touted as a revolutionary weed control for peanut and soybean crops, because it was designed to be applied once to the soil as a "pre-emergent" prior to the planting of peanut seeds. From then until the peanuts were harvested, the farmer would not need to apply any other herbicide to control noxious weeds that compete with peanuts for important nutrients. The active ingredient in Strongarm, diclosulam, was supposed to attack the roots of "target" weeds, inhibiting their growth, without affecting the "non-target" peanut crop. JA 120. Beginning in the early 1990s, however, Dow scientists learned through field tests that the absorption rate for a herbicide similar to diclosulam was significantly hindered when the soil has a pH level above 7.0. *See* R.G. Lehmann *et al.*, *Degradation of a Sulfonamide Herbicide as a Function of Soil Sorption*, 32 Weed Research 197 (1992) (CA App. 597). Later studies by Dow scientists established that, the higher the soil pH, the less likely diclosulam was

[5] As an appeal from a summary judgment for Dow, the record facts must be construed in the light most favorable to petitioners. *See Wolston v. Reader's Digest Ass'n, Inc.*, 443 U.S. 157, 162 n.5 (1979). Because Dow's motion was based on federal preemption, "no pre-trial discovery was undertaken in this case." Dow Cert. Opp. 3.

to be absorbed in the ground and thus the higher the "effect" of the herbicide on plant life exposed to the chemical. *See* J. Zabik *et al.*, *Terrestrial Field Dissipation of Diclosulam at Four Sites in the United States*, 49 J. Agric. Food Chem. 3284 (2001) (CA App. 590); JA 124. Thus, when soil pH levels reached 7.0 or greater, the Strongarm in the soil would not be readily absorbed and would retard or injure the roots of the non-target peanut plants. JA 126.

Despite those known deficiencies, Dow widely touted the putative benefits of its new pesticide. In 1999, before EPA had registered Strongarm, the Texas Department of Agriculture was sufficiently impressed by Dow's representations that it requested a special exemption to use Strongarm on 184,000 acres, or roughly half of the State's peanut crop. *See* 64 Fed. Reg. 9152, 9152 (1999).[6]

Although EPA declined the State's request, it "conditionally registered" Strongarm on March 8, 2000. JA 63-93. Because peanuts mature on a 150-day growing cycle, seeds in west Texas must be planted on or about May 1 of each year. Dow thus had to act quickly to convey information about Strongarm so that it could be sold for the 2000 planting season. At a series of "Field Days" sponsored by Texas agricultural extension agents employed by Texas A&M University and conducted in 1999 and 2000, Dow agents orally recommended Strongarm to Texas peanut farmers. *See, e.g.*, JA 147-48, 152-53, 157-58.

Petitioners, farmers who grow their crop principally for sale as packaged peanuts at baseball games and other sporting events, decided to use Strongarm on the basis of those oral presentations. *See, e.g.*, JA 148, 153, 158. It is common in Texas agriculture for farmers to hire their local agricultural supplies outlet or custom chemical applicator to apply the pesticide for them, rather than applying the pesticide themselves. Those applicators, in turn, will mix

[6] Texas has 320,000-370,000 acres of peanut farmland and ranks second nationally in peanut production. *See* Texas Agric. Ext. Serv., *Texas Peanut Production Guide* 1 (Apr. 2001) ("*Texas Peanut Guide*").

and distribute the pesticide via methods such as sprinkler outlets that they use on the farmers' land or move from farm to farm. In this manner, the farmer contracts out the task of applying pesticides without directly purchasing the pesticide or being aware of the label's contents. In any event, the Strongarm label was in plastic sealing that could not be opened or read until after purchase. *See, e.g.*, JA 148.

Within weeks after planting their peanut seeds on or about May 1, the farmers discovered signs of herbicide damage to their crops. Plants "treated with Strongarm were not growing normally, were stunted in their growth, were yellowed and discolored and were not developing foliage." *E.g.*, JA 153, 158; *see* JA 121. At this point, the farmers had applied no chemical to their land other than Strongarm, and they had no reason to suspect that the high pH content of their soil was a factor. JA 153, 158; *see also* JA 125-26, 139, 148, 158.

When the farmers contacted Dow to complain about the effects of Strongarm on their crop and to ask what they should do, Dow officials came to inspect the fields. *See, e.g.*, JA 139, 153. Those agents were able to observe a "burning" of the farmers' crop roots and made oral representations as follows: the farmers were advised to "grow out" their crop and keep a record of their extra expenses. *See, e.g.*, JA 153, 161-62. Dow would compensate them for those costs, as well as any damages they suffered from using Strongarm. *See, e.g.*, JA 148, 162.

By June, the farmers were in a terrible bind. They had little choice at that point but to follow Dow's instructions. The Strongarm was so toxic in their soil that they could not reasonably plow up their peanut plants and plant a different crop, even if their agricultural lenders would have permitted them to do so. But they could tell from the stunted growth of their peanut plants that maturation of the crop would be significantly delayed. Adding to the farmers' difficulties was that Strongarm failed to control noxious weed infestations as promised; the farmers

incurred additional costs in applying other herbicides to combat weeds and additional water to counteract the burning effect of Strongarm.

The resultant stunting of the farmers' crops created special weather-related problems. Most of the affected farms were in west Texas, where autumnal freezing rains make it imperative to harvest the peanuts by approximately October 1 to achieve the best crop. *See Texas Peanut Guide* at 10 (noting that delays in maturation of peanuts "reduce yield and quality and increase the risk of freeze damage and late season drought to peanuts"). Peanuts grow underground and are harvested by tilling up the crops and having them dry above ground. Hot, dry weather is essential to the harvesting process. But, when the stunted plants were not ready to be harvested by October 15, the farmers faced the prospect that, even if their peanuts eventually grew properly to maturity, they would have to harvest them in the fall rainy season, and the crops would be severely damaged or ruined above ground.

In late 2000 – before any new studies could have been completed and before any petitioners had sent demand letters to Dow formally seeking compensation for Strongarm-related injuries – Dow re-registered its Strongarm label with EPA, which approved the amendments on January 30, 2001. JA 123, 181. In that re-registration, Dow altered the label in multiple, significant ways. First, Dow registered a "supplemental" label that was for "distribution and use only in the states of New Mexico, Oklahoma and Texas," JA 179, the three states whose peanut farmers had experienced crop damage from Strongarm in 2000. Second, Dow explicitly stated: "Do not apply Strongarm to soils with a pH of 7.2 or greater." JA 181. (The soil on many petitioners' lands has a pH level of that amount or higher. *See* JA 125.) Third, Dow stated on the new supplemental label that the amount of Strongarm to be applied was .3 to .45 ounces per acre, as opposed to the .45 ounces per acre directed on the label conditionally approved by EPA on March 8, 2000. *Compare* JA 179 *with*

JA 75. Fourth, whereas the original label said nothing about the need for additional applications of herbicides for weed infestations other than nutsedge, *see* JA 87, the supplemental label noted that, "[w]hen using the 0.3-oz rate, weed control results on eclipta, morningglory, nutsedge, and Virginia copperleaf may be variable. A follow up treatment with another herbicide may be necessary for full season control." JA 180. Finally, rather than applying Strongarm prior to planting, the supplemental label stated that the pesticide should be applied *after* planting. JA 176, 180. "Many of the west Texas farms reported peanut injury with preplant incorporation." JA 124.

By the time EPA had conditionally approved Dow's supplemental label for Strongarm in early 2001, the farmers had an idea of the additional expenses and damages they had suffered as a result of the disastrous experiment with Strongarm, although some farmers also discovered that the lingering effects of the Strongarm in their soil impaired their 2001 crops of wheat and cotton (rotated with peanuts for soil regeneration). JA 127. But, when they presented this information to Dow, as its agents had instructed them, Dow refused to pay for the "year 2000 production loss as they promised to do." *E.g.*, JA 139. Beginning in late September 2001, a few petitioners wrote officially to inform Dow of their damages, request payment, and advise that, if no satisfaction was forthcoming, they would file suit in state court to recover their damages. *See, e.g.*, JA 36-39. Throughout the autumn, more farmers came forward to advise Dow of the problems they had experienced and to request formally that Dow honor its promise to make whole the farmers who had been damaged by using Strongarm. *See, e.g.*, JA 33-34. Under the Texas Deceptive Trade Practices Act ("DTPA"), Tex. Bus. & Com. Code §§ 17.01 *et seq.*, the farmers were required to provide written notification to Dow before they could bring suit in state court. The DTPA provides that no suit filed within 60 days of that notification shall be effective. On December 21, 2001, before the 60 days had expired for the

vast bulk of petitioners, Dow filed suit in federal district court for a declaratory judgment that all of the farmers' claims were preempted by FIFRA. *See* JA 13-23.

6. When Dow sued for declaratory relief, the farmers brought counterclaims asserting various state-law claims, including: strict liability in tort for a defective product; fraud and fraud in the inducement arising out of Dow's knowledge that Strongarm was particularly toxic in high pH soils from prior studies and the post-application representations by Dow officials that they would compensate the farmers for any harm that occurred to their crop from permitting it to grow out; a DTPA claim for deceptive practices in connection with the statements Dow had made to the farmers after Strongarm had been applied to and damaged their crops; estoppel and waiver, on the ground that Dow's contradictory oral off-label representations precluded Dow from relying on its label; negligent misrepresentation; breach of express and implied warranty; negligence; and breach of contract. *See* JA 183-93.

The district court granted Dow's motion for summary judgment, holding nearly all of the farmers' claims preempted. Pet. App. 21a. The one exception was that FIFRA did not preempt claims based on "statements made by [Dow's] employee representatives who examined [petitioners'] fields and advised them that the peanuts would grow out of the problem and that [Dow] would pay the growers for any production loss and increased expenses." *Id.* at 28a-29a. But the court held the farmers limited to the remedies specified on the label. *Id.* at 29a-30a.

The court of appeals affirmed, holding that "FIFRA expressly preempted the farmers' state law claims." *Id.* at 9a. It rested on circuit precedents announcing a rule that "FIFRA preempts state laws that either directly or indirectly impose different labeling requirements." *Id.* at 11a & n.9 (citing *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 (5th Cir. 1994)). The court reasoned that "the farmers' claims are expressly preempted under § 136v(b) if a judgment against Dow would induce it to alter its product

label," *id.* at 15a, even as to the "off label" claims, *id.* at 16a. It held that the farmers' claims were "all preempted by FIFRA's express preemption clause." *Id.* at 20a.

SUMMARY OF ARGUMENT

I. State damages actions are not preempted by FIFRA because the word "requirements" as understood by its context in § 136v(b) encompasses only rules issued pursuant to positive law, such as statutes and regulations. Section 136v(b) is a subset of a broader non-preemptive provision in § 136v(a), which expressly upholds the authority of States to issue "regulation[s]." By referring to "Such State" in § 136v(b), Congress specifically referred back to the regulations authorized in § 136v(a).

That construction is consistent with the broad non-preemptive thrust of § 136v(a), as well as the overall structure of FIFRA. The word "requirements" appears 75 times in the statute: in every instance, the word clearly refers to a duty imposed solely by positive law and not common law. FIFRA is therefore unlike statutes using word "requirements" that this Court considered in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). The legislative history contains no indication that Congress intended to upset long-standing practices in States permitting compensatory damages suits against pesticide manufacturers that caused crop damage. To construe § 136v(b) as preempting the farmers' suits would be contrary to Congress's central aim in the 1972 Act to protect the public from dangerous chemicals. Because nothing in FIFRA affords compensation to parties injured by pesticides, state-law damages claims properly fill the void left by Congress.

II. Even if the Court were to conclude that "requirements for labeling or packaging" in § 136v(b) can encompass some state-law claims, the scope of § 136v(b) permits claims against pesticide manufacturers that challenge the efficacy of the product even where such efficacy claims are made on the label. In 1978, Congress expressly authorized EPA to waive determinations of whether a pesticide is efficacious, and for a quarter-century the agency has in fact waived such requirements. Thus, claims contesting the efficacy of a pesticide impose no "requirements for labeling or packaging in addition to or different from" FIFRA.

That is also true with respect to misbranding. It is unlawful under FIFRA for a manufacturer to label a pesticide with false information, improper instructions for use, and inadequate warnings. State-law claims that are consistent with that federal prohibition are therefore not preempted. *See Medtronic*, 518 U.S. at 495; *id.* at 513 (O'Connor, J., concurring in relevant part).

In any case, many of the farmers' specific claims – such as strict liability, negligent design, fraud, and deceptive trade practices – rest on representations by Dow having nothing to do with the Strongarm label and cannot be defended with any type of "fair warning." Those claims therefore impose no additional or different labeling requirements merely because the manufacturer makes a voluntary decision to change its label and thereby seek to avert its future liability to other purchasers. The Fifth Circuit fundamentally disregarded this Court's teaching that the proper analysis focuses on the legal duty underlying each state-law claim, and not on the open-ended inquiry into whether a damages award might somehow "induce" a manufacturer to seek a change in its label from EPA. *See Cipollone*, 505 U.S. at 523-30 (plurality op.); *Medtronic*, 518 U.S. at 492-502.

III. The farmers are entitled to sue for misrepresentations that Dow made after they used Strongarm. Dow represented that it would compensate the farmers for their damages from crop loss and expenses incurred in trying to salvage their crops. By holding that "all" of the farmers' claims are preempted, Pet. App. 20a, the Fifth Circuit's internally contradictory opinion forecloses the farmers' ability to sue for those broken promises and misrepresentations in an amount beyond the label's limitation of remedies, even though those claims do not implicate Dow's Strongarm label or any other FIFRA requirement.

ARGUMENT

I. STATE-LAW DAMAGES ACTIONS ARE NOT PREEMPTED BY FIFRA

For six decades prior to the 1972 Act, farmers routinely brought state-law actions against manufacturers for damages to their crops caused by pesticides. Nothing in the text, structure, legislative history, or purposes of that Act indicates that Congress intended to change that tradition by precluding farmers from seeking redress for the damages caused to them by pesticide manufacturers.

A. The Text Of § 136v(b) Does Not Compel Preemption Of The Farmers' Claims

As with any statute, "analysis of the scope of the preemption statute must begin with its text." *Medtronic*, 518 U.S. at 485. Although the existence of an express preemption clause does not negate the need for an analysis of implied preemption, *see Freightliner Corp. v. Myrick*, 514 U.S. 280, 288-89 (1995), analysis of the clause itself "must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent," *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993).

The preemption clause at issue here follows immediately after a provision that confers significant regulatory authority on States. Together those provisions read:

> **§ 136v. Authority of States**
>
> **(a) In General**.—A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this [Act].
>
> **(b) Uniformity**.—Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this [Act].

The theory underlying preemption is that state-law claims, such as the farmers' damages claims here, impose "requirements for labeling or packaging in addition to or different from those required under [FIFRA]." § 136v(b). But the text of § 136v(b) and § 136v(a) does not support preemption of such claims.

1. "Requirements" in § 136v(b) is a subset of "regulation[s]" in § 136v(a)

The word "requirements" in § 136v(b) is used as a subset of the word "regulation[s]" in § 136v(a). A State is permitted to "regulate" (§ 136v(a)) the sale or use of pesticides, but only to the extent "[s]uch State" (§ 136v(b)) does not impose "requirements" (*id.*) that are in addition to or different from those in FIFRA. The "requirements" of § 136v(b), therefore, are viewed through the lens of the "regulation[s]" a State is permitted to issue in § 136v(a). *See Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995) ("a word is known by the company it keeps").

As this Court has unanimously concluded, the term "regulations" denotes "positive enactments." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 63 (2002). *See also Cipollone*, 505 U.S. at 519 ("the term 'regulation' most naturally refers to positive enactments by [legislatures and agencies], not to common-law damages actions"). As used in FIFRA, the term "regulation" is used the same way, for it would make no sense to say that a damages award acts as a "requirement" to "permit any sale or use prohibited by [FIFRA]." § 136v(a). To be sure, a state statute authorizing the sale or use of any state-registered pesticide would constitute a preempted "regulation" or "requirement" as to pesticides prohibited by EPA under FIFRA, but no court judgment could grant the same sale or use permission, which is purely a function of positive law. Whatever limits § 136v may impose on positive state labeling commands,

therefore, that section contains no textual indication of an intent to preempt state damages actions.[7]

In addition, Congress used the term "requirements" in § 136v(b) to refer to both state and FIFRA requirements. It prohibits state labeling "requirements" in addition to or different from "those required" (*i.e.*, "those [*requirements*] required") under FIFRA. It would be unnatural to read the word "requirements" more broadly in reference to a source of state law than for the federal government. *See Mohasco Corp. v. Silver*, 447 U.S. 807, 826 (1980) ("[W]e cannot . . . giv[e] the word 'filed' two different meanings in the same section of the statute.").

2. The preemptive "requirements" in § 136v(b) are narrow exceptions to broad regulatory authority conferred on States by § 136v(a)

The preemptive scope of § 136v(b) must be assessed in the context of § 136v(a), which is an "anti-preemption" provision that expressly authorizes States to regulate pesticides *more* stringently than EPA. Thus, a State (such as Texas) may completely ban the sale or use of a pesticide (such as Strongarm), even though EPA has registered the pesticide and approved its label. (A State, however, may not override federal law by permitting "any sale or use *prohibited by* [FIFRA]." § 136v(a) (emphasis added).)

As this Court stressed in *Mortier*, "§ 136v(a) . . . acts to ensure that the States could continue to regulate use and sales even where, such as with regard to the banning of mislabeled products, a narrow pre-emptive overlap might occur." 501 U.S. at 614. Plainly it makes no sense to con-

[7] This Court has squarely held that "field pre-emption cannot be inferred" from FIFRA. *Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 612 (1991). "To the contrary, the statute leaves ample room for States and localities to supplement federal efforts even absent the express regulatory authorization of § 136v(a). . . . The specific grant of authority in § 136v(a) . . . does not serve to hand back to the States powers that the statute had impliedly usurped." *Id.* at 613-14. It therefore is logical to read § 136v(a) and (b) as not intending to affect the common-law authority that States exercised prior to the 1972 Act.

strue § 136v(b) to foreclose the *lesser* regulatory effects that flow from damages actions that enable the pesticide manufacturer to choose to sell its products while assuming the risk of incurring common-law liability, when § 136v(a) gives States the far *greater* power to ban altogether sales and uses of the same product. Notably, the statutes at issue in *Cipollone* and *Medtronic* did not contain similar provisions conferring such sweeping regulatory authority on States, so this Court did not address whether Congress intended "requirements," in a statutory context analogous to FIFRA, to encompass the less stringent rulemaking directives of common-law liability.

3. Section 136v(b) addresses label commands, not actions that indirectly induce label changes

The limited scope of § 136v(b) also must be understood in light of the interplay between that provision and § 136v(a) and (c), which authorize States to apply indirect pressure on pesticide manufacturers that might induce a change to their labels. Holding state-law claims preempted is contrary to that intent.

Section 136v(a) permits a State to restrict or completely prohibit pesticide sales and use for any reason – including the State's perception that the label's warning is inadequate or the product is misbranded. Like a substantial damages award, those restrictions may induce pesticide manufacturers to seek EPA approval for a label alteration. Alternatively, a manufacturer may be induced to request EPA approval to change its label to promote additional pesticide uses approved by States under § 136v(c) that EPA has not approved. Section 136v(c) acts as an exception to § 136v(b) by conferring additional authority on States with respect to pesticide registrations to meet "special local needs." § 136v(c)(1). Indeed, EPA has interpreted § 136v(c) to permit States *directly* to "require supplemental labeling" when they determine a pesticide should be classified for restricted use under state law but EPA has not done so under FIFRA. 40 C.F.R. § 162.153(e)(5); *see* 46 Fed. Reg. 2008, 2011-12 (1981).

Especially in view of such authority for direct labeling regulations, any indirect pressure to change a pesticide label does not frustrate Congress's purpose of establishing nationally uniform labels. If a State bans the use of a pesticide, then any change the manufacturer makes to the label (as approved by EPA) would not be preempted; there is no reason to treat labeling changes prompted by state-law damages liability any differently. Indeed, Dow's own actions here suggest that "uniformity" concerns can readily be accommodated. After causing devastating injury to the farmers' crops, Dow rushed through a "supplemental" label addition within *seven months* after the farmers first reported injury. That supplemental label – which states that it is for distribution *only* in Texas, New Mexico, and Oklahoma – advised growers in those states with lands having a soil pH of 7.2 or greater not to use the very product that Dow had warranted the year before as usable "in all areas where peanuts are grown," JA 175, and to use it in a substantially different manner in lesser pH soils.

Congress commonly distinguishes between state positive and common law for preemption purposes. For example, the Court recently found no preemption of common-law claims under the Federal Boat Safety Act, noting that construing the Act that way "does not produce anomalous results. It would have been perfectly rational for Congress not to pre-empt common-law claims, which – unlike most administrative and legislative regulations – necessarily perform an important remedial role in compensating accident victims." *Sprietsma*, 537 U.S. at 64. The Court unanimously reached that conclusion in construing a preemption provision with a more definitive preemptive scope than FIFRA: "a State may not establish, continue in effect, or enforce a law or regulation establishing . . . or imposing a requirement." *Id.* at 58-59.[8]

[8] *See also Cipollone*, 505 U.S. at 518 ("[T]here is no general, inherent conflict between federal pre-emption of state warning requirements and the continued vitality of state common-law damages actions."); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185-86 (1988) ("The

4. Section 136v(b) must be construed applying the presumption against preemption

Any doubt about Congress's intent in using the word "requirements" – or in construing the scope of § 136v(b), *see infra* Parts II and III – must be resolved *against* preemption. The Court has "long presumed that Congress does not cavalierly pre-empt state-law causes of action," especially where "Congress has 'legislated . . . in a field which the States have traditionally occupied.'" *Medtronic*, 518 U.S. at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).[9] Agriculture and consumer protection are plainly such "traditional" state-law fields.

As this Court said in the FIFRA context in *Mortier*, preemption analysis "'start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" 501 U.S. at 605 (quoting *Rice*, 331 U.S. at 230). The *Mortier* Court then applied that long-standing presumption against federal preemption of state law by holding that FIFRA does not preempt pesticide regulation by local governments, even though § 136v expressly authorizes "States" to regulate pesticides but is silent with respect to whether local governments may also do so. The Court found § 136v's "[m]ere silence" on the question "wholly inadequate to convey an express preemptive intent." *Id.* at 607. Here, too, the statute is

effects of direct regulation . . . are significantly more intrusive than the incidental regulatory effects of such an additional award provision. . . . Congress may reasonably determine that incidental regulatory pressure is acceptable, whereas direct regulatory authority is not."); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984) ("Congress intended to stand by both concepts [of federal regulation and state damage liability] and to tolerate whatever tension there was between them. We can do no less.").

[9] *See also, e.g., New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654-55 (1995) (applying presumption and finding no preemption) (citing *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985)); *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 740 (1985).

silent on preemption of damages claims, and congressional purposes underlying FIFRA are not served by broadly construing "requirements" to foreclose the types of state-law claims that were routinely brought against manufacturers to redress injuries caused by pesticides.

B. FIFRA's Structure Confirms That Congress Did Not Intend To Preempt State-Law Claims

The extensive use of "requirements" throughout FIFRA shows that Congress had no intent to preempt damages actions that might indirectly spur a pesticide manufacturer to alter the label of a faulty product. The term "requirements" is used 75 times in the remainder of FIFRA, including in the context of both labeling and state-law requirements, and each time refers only to direct commands arising out of statutory or regulatory enactments.

The use of "requirements" throughout FIFRA demonstrates that Congress understood labeling "requirements" to refer only to labeling commands imposed by statute and regulation, and it used the term "requirements" to denote a subset of "regulation[s]," a term connoting positive commands of law. "Requirements" should be construed the same way in § 136v(b). *See, e.g., Ratzlaf v. United States*, 510 U.S. 135, 143 (1994) ("A term appearing in several places in a statutory text is generally read the same way each time it appears."); *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 479 (1992) ("identical terms within an Act bear the same meaning").

For example, EPA may register a pesticide only if "its labeling . . . compl[ies] with the requirements of [FIFRA]." § 136a(c)(5)(B). A pesticide is "misbranded" if its "labeling" fails to conform to the classification "requirements" imposed by § 136a(d). § 136(q)(1)(F), (G). Another provision, entitled "Requirements," bars pesticide labels that "conflict with or detract from any statement required by law or the Administrator as a condition of registration." § 136a(c)(9)(B). And § 136q(a)(1)(B) provides that EPA regulations "may require" that "the labeling of a pesticide contain requirements and procedures for the transportation, storage, and disposal of the pesticide." Because FIFRA refers exclusively to labeling "requirements" imposed under that Act, § 136v(b) should not be read more broadly to encompass state-law damages actions.

FIFRA's numerous other uses of the term "requirements" likewise encompass only positive law. Various provisions refer specifically to FIFRA's own "data requirements,"[10] "recordkeeping requirements" (§§ 136f(a), 136i-1(a)), "time requirements" (§§ 136d(b), 136w(a)(2)(C), 136w(d)(1)), and "registration requirements" (§§ 136a(h), 136m(a)(2)(A)). Additional references point to the "requirements" found in specific sections of FIFRA.[11] Other

[10] *See* § 136a(c)(2)(A) ("data requirements . . . with respect to minor uses"); § 136a(c)(2)(B)(viii)(I)(A) ("data requirements" for registration); § 136a(c)(2)(B)(viii)(III) ("process to . . . alleviat[e] future disparities between Federal and State data requirements"); § 136a(c)(2)(E) (EPA "may waive otherwise applicable data requirements"). Other provisions address "data requirements." § 136a(h)(4)(B); § 136a-1(a)(1), (b)(4), (c)(1)(C), (f)(1), (f)(1)(B); § 136d(f)(3)(D), (f)(4); § 136q(a)(1).

[11] *See* § 136(q)(1)(F) (pesticide is "misbranded" if label omits § 136a(d) "requirements"); § 136(q)(1)(G) (same); § 136a(b)(2) ("requirements" of an experimental use permit); § 136a(c)(2)(B)(iv) ("requirements that served as a basis for the notice of intent to suspend"); § 136a(c)(6) (denial of registration for failure to satisfy "requirements" of § 136a(c)(5)); § 136a(g)(1)(A) ("requirements" of section 136d); § 136a(h)(3)(C) ("requirements" of § 136a(c)(3)); § 136a-1(a)(2) ("requirements" of § 136a(c)(5)); § 136a-1(e)(1)(A) ("requirements" of § 136a and "the regulations issued under such section"); § 136a-1(e)(1)(B) (same); § 136a-1(e)(1)(D) (same); § 136a-1(e)(4)(A)(iv) (same); § 136a-1(g)(2)(C) ("requirements" of § 136a(c)(5)); § 136a-1(j) (exemption from "requirements" of § 136a-1(d)-(f), (i)); § 136g(c)(1) (civil and criminal proceedings for failing to comply with requirements of this subchapter); § 136i-1(e) (requirements of this section do not affect state or federal laws); § 136j(b)(1) (exemption from penalties for compliance with requirements of this subchapter); § 136k(b)(3) (seizure of pesticides that cause harm but comply with requirements of this subchapter); § 136q(f)(1)(C) (exemptions from requirements of this subsection); § 136w(b) (exemption from requirements of this subchapter); § 136w-1(b) ("requirements" of § 136i).

references to "requirements" point to EPA regulations[12] and other federal statutes.[13]

Significantly, FIFRA's references to "requirements" *of state law* encompass only positive law commands. *See* § 136i(a)(1) ("[T]he Administrator, in consultation with the Governor of such State, shall conduct a program for the certification of applicators of pesticides. Such program shall conform to the requirements imposed upon the States under the provisions of subsection (a)(2) of this section . . . ."); § 136w-2(a) (referral of complaint to "State officials for their investigation of the matter consistent with the requirements of [FIFRA]"); *see also* § 136w-5 ("Each State may establish minimum requirements for training of maintenance applicators and service technicians."). And other provisions of FIFRA contain usage similar to § 136v(b)'s use of "requirements" as a subset of the positive-law "regulations" in § 136v(a). Thus, EPA "may by *regulation* . . . issue *requirements*" regarding pesticide storage and transportation. § 136q(a)(2)(A), (3)(A) (emphases added). It also "may by *regulation* . . . issue *requirements*" for disposing of certain pesticides and containers. § 136q(a)(2)(B)-(C), (3)(B)-(C) (emphases added). In sum, not a single one of the 75 uses of "requirements" from the 1972 Act or the 1978 amendments can be read to refer to common-law damages actions. Every use of "requirements" clearly encompasses commands imposed only by statute or regulation.

The *Medtronic* plurality similarly relied on the fact that neighboring subsections of the statutory provision at issue there – and unlike the statute at issue in *Cipollone* – used the term "requirements" to "refer only to statutory and

[12] *See* § 136a(h)(3)(A)(ii) ("[r]equirements" for proposed regulations addressing antimicrobial pesticides); § 136a(h)(3)(B)(iii) ("[r]equirements" for final regulations); § 136q(a)(2)(A)-(C) (EPA authority to "issue . . . requirements and procedures"); § 136q(a)(3)(A)-(C) (same).

[13] *See* § 136a-1(g)(2)(E)(ii) ("requirements" of Federal Food, Drug, and Cosmetic Act); § 136q(f)(1)(B)(iv) ("requirements" of Solid Waste Disposal Act); § 136q(f)(3) (same); § 136q(h)(1) (same).

regulatory law that exists pursuant to the [statute] itself, suggesting that the pre-empted 'requirements' established or continued by States also refer primarily to positive enactments of state law." 518 U.S. at 489. The textual evidence here, however, is far stronger than in *Medtronic*. There, the use of "requirements" in the preemption clause itself did not refer back specifically to regulations Congress authorized States to promulgate in the same manner as § 136v(b),[14] whereas here the scores of other uses of "requirements" in FIFRA support a uniform and consistent interpretation of "requirements" in § 136v as limited to those rules deriving from positive law enactments. *See also Sprietsma*, 537 U.S. at 63 (finding that "Congress preempted only positive enactments" based on context in which "law or regulation" appeared in provision).[15]

C. FIFRA's Legislative History And Purposes Reveal No Intent To Preempt Damages Actions

When FIFRA was amended in 1972 to add § 136v(b), state-law damages actions against manufacturers had been common since the advent of the chemical pesticide industry. *See supra* pp. 4-5. And it was well-settled that

[14] The preemption clause at issue in *Medtronic* addressed "State and local requirements" in the provision's title. The substantive provision stated that "'no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement . . . which is different from, or in addition to, any requirement applicable under this chapter to the device.'" 518 U.S. at 481 (quoting 21 U.S.C. § 360k(a)(1)). Unlike in § 136v(b), which cross-references a state "requirement" stemming from a "regulation" otherwise permitted in § 136v(a), the preemption clause in *Medtronic* contained no similar cross-reference.

[15] The Montana Supreme Court was persuaded by FIFRA's voluminous and consistent usage that § 136v preempts no common-law claims, and it observed that, despite the fact that many federal courts of appeals had held such claims preempted, none had "ever addressed the meaning of 'requirements' in the entire context of FIFRA . . . . It is inconceivable that Congress intended that § 136v(b) would be the only section of FIFRA in which the term 'requirements' includes the application of general rules of common law by judges and juries." *Sleath v. West Mont Home Health Servs., Inc.*, 16 P.3d 1042, 1051 (Mont. 2000).

FIFRA's labeling requirements set only minimum standards and thus did not preempt state-law damages actions for failure to warn.[16] Aware of that background, Congress thus perceived no need to include a private right of action for damages in FIFRA.

In *Mortier*, this Court held that the legislative history of § 136v(b) concerning whether local governments were preempted from regulating pesticides was "complex and ambiguous," 501 U.S. at 612, and that a "disagreement" on that issue between "the two principal committees responsible for the bill . . . falls far short of establishing that preemption of local pesticide regulation was the 'clear and manifest purpose of Congress,'" *id.* at 610. The history on the issue presented here is far clearer. According to a comprehensive review of the voluminous legislative history of the 1972 FIFRA amendments by the U.S. Department of Justice, no witness or Member of Congress ever suggested that the proposed legislation would shield pesticide manufacturers from product liability tort suits. *See* Amicus Br. for United States at 5-6, 18-19, *Etcheverry v. Tri-Ag Serv., Inc.*, No. S072524 (Cal. filed Mar. 23, 1999), *available at* https://www.citizen.org/documents/usetcheverrybrief.pdf. Indeed, there is not even a single mention of such a notion. *Id.* That omission is striking, given the testimony estimating the personal toll attributable to pesticides per year at 200 to 800 deaths and 60,000 to 80,000 injuries.[17] As the U.S. has concluded, "[g]iven

[16] *See, e.g., Hubbard-Hall*, 340 F.2d at 405 (no FIFRA preemption); *Griffin v. Planters Chem. Corp.*, 302 F. Supp. 937, 944 (D.S.C. 1969) ("Aside from the requirements set forth for the label by the Secretary of Agriculture, [defendant] had a duty to use a label, or furnish a warning commensurate with the danger."); *Rumsey v. Freeway Manor Minimax*, 423 S.W.2d 387, 394 (Tex. Ct. App. 1968) (FIFRA does not "purport[] to change the common law duty to warn . . . [but] merely set[s] minimum standards").

[17] *See Federal Pesticide Control Act of 1971: Hearings before the House Comm. on Agriculture*, 92 Cong., 1st Sess. 708 (1971); *Federal Environmental Pesticide Control Act: Hearings before the Subcomm. on Agricultural Research and General Legis. of the Senate Comm. on Agriculture and Forestry*, 92 Cong., 1st Sess. 161, 168-71, 172-86 (1971); H.R. Rep. No. 92-511, at 71 (1971); S. Rep. No. 92-970, at 27 (1972).

that FIFRA establishes no private damages remedy for those injured by pesticides, it would be astonishing that, without any discussion, Congress could have intended to deprive injured persons of all means of relief." *Id.* at 6; *Silkwood*, 464 U.S. at 256. *See also* Amici Br. for Western Peanut Growers Ass'n *et al.*

The *Medtronic* plurality rejected a similar argument under the Medical Device Amendments, finding the argument for preemption "not only unpersuasive, [but] implausible." 518 U.S. at 487. Absent a federal private cause of action, preemption of state-law damages actions would effectively bar compensatory relief to injured persons and "would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation." *Id.* In view of the industry's position that any such liability would induce a change in the pesticide's label, affirming the Fifth Circuit's decision would produce a similarly perverse effect under FIFRA.

D. Neither The Fifth Circuit's Nor The Government's New Preemption Analysis Is Persuasive

Like other courts that have upheld a broad preemption under FIFRA, the Fifth Circuit assumed that § 136v(b)'s use of the word "requirements" necessarily ends the analysis. *See* Pet. App. 11a (citing *Andrus v. AgrEvo USA Co.*, 178 F.3d 395, 398 (5th Cir. 1999)). The court made no effort to consider the contextual placement of "requirements" in the preemption provision, as this Court did in *Medtronic*, or the overwhelming textual and contextual evidence that Congress could not possibly have meant to foreclose state lawsuits when it used the word "requirements" in § 136v(b).

In that respect, the court below followed mechanistically other court of appeals' decisions finding that FIFRA preempts state failure-to-warn damage claims, many of which

were decided before *Medtronic*. Those cases in turn had applied *Cipollone* based largely on the fact that "requirements" appeared in both statutes. They made no serious examination of the very different statutory text and structure of FIFRA.[18] Even after this Court decided *Medtronic* – which made plain that "requirements" must be interpreted in its statutory context – some courts have considered themselves bound by pre-*Medtronic* precedent (and declined to rehear the issue *en banc*). *See, e.g., Netland v. Hess & Clark, Inc.*, 284 F.3d 895, 899 (8th Cir. 2002).

In *Etcheverry*, the United States recognized that the prevailing approach among federal courts contained no analytic force. In a powerful brief, the government argued that § 136v(b)'s use of "requirements" did not foreclose state-law actions to redress pesticide injuries. The government now has adopted a position 180 degrees opposite to its careful, detailed, and analytical brief in *Etcheverry*, which it reiterated in *Hart v. Bayer Corp.*, 199 F.3d 239 (5th Cir. 2000). Because the government's *amicus* briefs filed in *Etcheverry* and *Hart* were filed with the Solicitor General's authorization, *see* 28 C.F.R. § 0.20(c), the government's reversal of position now is entitled to no weight or deference. *See, e.g., Norfolk S. Ry. v. Shanklin*, 529 U.S. 344, 356 (2000) ("no such deference is appropriate" where government's position "contradicts the agency's own previous construction"); *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (degree of deference depends, *inter alia*, on consistency and formality of government's position).

[18] *See, e.g., King v. E.I. DuPont De Nemours & Co.*, 996 F.2d 1346, 1350-51 (1st Cir. 1993); *Worm v. American Cyanamid Co.*, 5 F.3d 744, 747 (4th Cir. 1993); *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1023-25 (5th Cir. 1994); *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 370-71 (7th Cir. 1993); *Bice v. Leslie's Poolmart, Inc.*, 39 F.3d 887, 888 (8th Cir. 1994); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 559-61 (9th Cir. 1995); *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 981 F.2d 1177, 1178-79 (10th Cir. 1993); *Papas v. Upjohn Co.*, 985 F.2d 516, 518 (11th Cir. 1993) (per curiam).

II. PETITIONERS' CLAIMS ARE OUTSIDE THE SCOPE OF § 136v(b) PREEMPTION

Even if this Court were to conclude that the word "requirements" in § 136v(b) can include state-law damages actions, it does not follow that *all* such claims are barred. The 1972 Act did not "transform[] FIFRA into a comprehensive statute that occupied the field of pesticide regulation." *Mortier*, 501 U.S. at 612. Yet Dow's theory of preemption, as accepted by the court below, would functionally do that: any claim with even an "indirect[]" effect (Pet. App. 11a) on a label is preempted. The court failed to conduct a nuanced analysis of the farmers' claims to determine whether they are consistent with § 136v(b).

For three distinct reasons, those claims survive. *First*, Congress specifically amended FIFRA to eliminate a requirement that EPA evaluate a pesticide's efficacy, so § 136v(b)'s "requirements" do not properly encompass common-law claims addressing efficacy. *See Medtronic*, 518 U.S. at 484-85 (interpreting scope of express preemption provision in light of congressional purposes and presumption against preemption); *id.* at 507-08 (Breyer, J., concurring in part and in the judgment) (scope of word "requirement" should be informed by "read[ing] the pre-emption statute . . . in light of . . . basic pre-emption principles" of "'conflict' and 'field' pre-emption"); *Cipollone*, 505 U.S. at 518 (using conflict-preemption analysis to interpret scope of express preemption clause in 1965 Federal Cigarette Labeling and Advertising Act). *Second*, Congress flatly prohibited labels that are false and give inadequate instructions for use. The farmers' claims are parallel to, and not inconsistent with, those "misbranding" requirements. *See Medtronic*, 518 U.S. at 495; *see also id.* at 513 (O'Connor, J., concurring in relevant part) (state cause of action that seeks to enforce federal requirement not preempted). *Third*, the text of § 136v(b) itself only forecloses state requirements that are "in addition to or different from" "labeling or packaging" requirements imposed under FIFRA. Analysis of the elements of the farmers'

claims – which the court below did not conduct – establishes that strict liability, breach of express warranty, negligence, and fraud claims rest on legal duties that impose no alteration to an EPA-approved label.

A. EPA Has Waived Evaluation Of Whether A Pesticide Might Be Toxic To The Target Crop When Approving A Pesticide Label

Congress has expressly permitted EPA to waive any evaluation of the efficacy of pesticides prior to registration. Because FIFRA no longer imposes a duty on EPA to evaluate the efficacy of any federally registered pesticide, liability for the farmers' claims imposes no labeling requirements "in addition to or different from" those in FIFRA. The "requirements" preempted in § 136v(b), therefore, cannot include claims concerning the efficacy of pesticides. Yet the farmers' claims here for strict liability, fraud, negligence, and breach of warranty *are*, in effect, claims that Strongarm was ineffective.

1. For the past 26 years, Congress has expressly authorized EPA to register agricultural pesticides *without* evaluating whether they might cause crop damage. EPA regulations provide that a pesticide manufacturer need not submit "efficacy" data concerning: (1) "target area phytotoxicity," which is defined as whether the pesticide leaves the target crop unharmed, 40 C.F.R. § 158.540, or (2) "product performance," defined as whether the pesticide controls the target pest, *id.* § 158.640(b); *see also* U.S. Inv. Br. 4.[19] As applied to this case, those regulations mean that EPA registered Strongarm without evaluating whether it might (1) damage the farmers' peanut crop or (2) control the weeds it was designed to eradicate.

[19] Although EPA's regulations provide that "target area phytotoxicity" data are "required for Special Review and certain public health situations," 40 C.F.R. § 158.540(b)(1), and "product performance" data are required in certain cases concerning human health or where EPA on a case-by-case basis requires it, *id.* § 158.640(b)(1), those circumstances are inapplicable here.

FIFRA's 1972 amendments allowed EPA to register a pesticide only upon evaluating its proposed label and determining that its "composition is such as to warrant the proposed claims for it." § 136a(c)(5)(A). But EPA soon discovered that efficacy review diverted scarce resources from the agency's paramount responsibilities of protecting public health and the natural environment, so it requested from Congress the authority "to waive the efficacy data requirement when appropriate" – "particularly [with regard to] agricultural pesticides." H.R. Rep. No. 95-343, at 9 (statement of EPA Administrator Costle); *see also* H.R. Rep. No. 95-663, at 18 (1977) ("The registration and reregistration process, which is the foundation of the program, has come to a virtual halt.").

In 1978, Congress amended FIFRA by conferring on EPA the authority it had requested to waive efficacy requirements. *See* § 136a(c)(5) (final two sentences). Congress made clear that "[t]his authority is expected to be used, in particular with respect to *agricultural chemicals*." H.R. Rep. No. 95-663, at 19 (emphasis added); *see also id.* at 27 (authorizing waiver "whenever the Administrator found that some other procedure for assuring the efficacy of pesticide products appeared to be sufficient").

EPA waived its review of proposed label claims relating to pesticide efficacy, explaining that the waiver would enable it to focus on EPA's "primary mandate under FIFRA . . . [,] the health and safety aspects of pesticides." 47 Fed. Reg. 53,192, 53,196 (1982); *see* 40 C.F.R. § 158.640(b)(1); 40 C.F.R. § 158.540(b)(1). The agency found that efficacy review was unnecessary because efficacy claims are "effectively regulated by the marketplace." 44 Fed. Reg. 27,932, 27,938 (1979). That is, "pesticide producers are aware that they are potentially subject to *damage suits* by the user community if their products prove ineffective in actual use." 47 Fed. Reg. 40,659, 40,661 (1982) (emphasis added). As a result, EPA reviews pesticide labels for the adequacy of claims relating to human health and the natural environment – but *not* for "target area phytotoxic-

ity," *i.e.*, the farmers' crop damage. 40 C.F.R. § 158.540. Accordingly, there is no EPA action, rule, or decision that would conflict with the farmers' suit.[20]

In 1996, after several courts had found crop damage claims preempted by FIFRA based on EPA's supposedly "rigorous label-approval process," *Taylor AG Indus.*, 54 F.3d at 560, EPA issued a public notice ("PR 96-4") explaining that "courts have erroneously concluded that because a pesticide label contained warnings regarding property damage that EPA had necessarily evaluated such warnings and found them to be truthful and adequate. . . . [T]his Notice is intended to clarify that EPA's approval of a pesticide label does not reflect any determination on the part of EPA that the pesticide will be efficacious or will not damage crops or cause other property damage." JA 235. EPA also noted that, in previously exercising its power to waive efficacy review, it had "pointed to private legal actions for damages as one factor that would ensure that pesticide manufacturers sold an efficacious product." JA 230 (citing 47 Fed. Reg. at 40,659, 40,661).[21]

[20] The Texas Supreme Court found these considerations persuasive in holding that FIFRA does not preempt crop damage claims. *See American Cyanamid Co. v. Geye*, 79 S.W.3d 21 (Tex. 2002), *cert. denied*, 123 S. Ct. 2637 (2003). Although the California Supreme Court reached a contrary conclusion, it did so based on a fundamental error that assumed EPA's efficacy data waiver did not include the "target area phytotoxicity" waiver in 40 C.F.R. § 158.540. *See id.* at 28-29 (discussing *Etcheverry v. Tri-Ag Serv., Inc.*, 993 P.2d 366 (Cal. 2000)). As the government recognizes, the "target area phytotoxocity" data waiver in 40 C.F.R. § 158.540 is part and parcel of EPA's efficacy data waiver pursuant to the 1978 FIFRA amendments. *See* U.S. Inv. Br. 4, 13.

[21] In attempting to rationalize its changing position on FIFRA preemption, the government observes that PR 96-4 was not intended to "express a view on the proper interpretation of the text of FIFRA's preemption provision." U.S. Inv. Br. 13-14 n.3. But the government cannot contest that the notice's statements regarding EPA's waiver of efficacy review are *factually* accurate. *See id.* ("[PR 96-4] makes clear that, under the general registration procedures addressed in that notice, EPA had waived review of the efficacy of agricultural pesticides in the registration process."); *id.* at 13 n.2 ("Generally, EPA does not independently evaluate a registrant's product efficacy claims pertaining to agricultural pesticides."); *accord* Letter from Jonathan Z. Cannon, General Counsel, EPA, to Douglas T. Nelson, Vice President-General Counsel, American Crop Protection Ass'n (Nov. 14, 1996) ("In the notice, EPA explains that it does not review the accuracy of label claims regarding efficacy and the potential for crop damage. . . . It appears to EPA that [certain court decisions] evidence a lack of a full understanding of EPA procedures and regulations.").

EPA's decision not to evaluate efficacy claims when registering a pesticide finds a strong parallel to *Medtronic*, where the Court unanimously found that FDA approval of a pacemaker, under a standard requiring the agency to determine only whether the device was "substantially equivalent" to another device already on the market, did not constitute a preemptive "requirement." 518 U.S. at 493-94; *see also id.* at 513 (O'Connor, J., concurring in relevant part). The preemption provision in that case applied to requirements concerning "safety or effectiveness." FDA even conducted its substantial equivalence review of the pacemaker with some regard for those concerns, but its abbreviated review did not "require" the pacemaker to take any particular form. *Id.* at 493 (majority op.). Instead, the device was approved without "running the gauntlet" of the full approval process for a novel medical device. *Id.* at 493-94.

2. EPA approved the Strongarm label without requiring Dow to take any particular form with respect to target area phytotoxicity claims. Because EPA waived that requirement, there was no FIFRA or EPA labeling "requirement" to preempt the farmers' suit.

The government suggests that Dow submitted efficacy data to EPA in seeking expedited review of its Strongarm application, but it then admits that such data were "*not* [submitted for EPA review] in the context of label approval." U.S. Inv. Br. 16 (emphasis added). Instead, it concedes Dow submitted data under an expedited review provision (called the "Reduced Risk Initiative") only "to allow [EPA] to determine whether 'risk reduction has a

reasonable opportunity to be accomplished by adoption of the new pesticide by growers.'" *Id.* at 16 n.5 (quoting EPA PR 97-3 (JA 252)); *see also id.* at 13 n.2 (describing EPA's consideration of efficacy data under RRI as "circumscribed"). The government does not contend that EPA actually concluded, based on any such data, that Strongarm was safe for crops (or that the agency had any duty to assess such data). It is illogical to infer that EPA would fully evaluate target area phytotoxicity data under an *expedited* review provision when it undisputedly does not do so in a full review. The agency's regulations make clear that, if "part 158" does not require submission of efficacy data (it does not), then EPA does *not* "determine[] that the composition of the product is such as to warrant the proposed efficacy claims for it." 40 C.F.R. § 152.112(d).

Dow, on the other hand, appears to claim that EPA evaluated Strongarm's efficacy and relies on an inapposite EPA reference to Dow's proposed peanut "'plantback restrictions'" (*i.e.*, the required interval of time before a new crop can be planted on the same land). Dow Cert. Opp. 2 (quoting 65 Fed. Reg. 12,129, 12,133 (2000)). But EPA's statement was not made in the context of a FIFRA registration or an evaluation of the potential for crop damage. Rather, it concerns the agency's evaluation of Dow's request to establish a safe tolerance for diclosulam in the *food* supply, pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 346 (entitled "Tolerances for poisonous or deleterious substances in *food*; regulations") (emphasis added). *See* 40 C.F.R. Pt. 180 (entitled "Tolerances and Exemptions from Tolerances for Pesticide Chemicals in *Food*") (emphasis added); *see also* JA 233 ("EPA's concern is that the consumption of the rotated crop would increase *dietary* exposure to the pesticide residue. Rotational crop restrictions are not reviewed to determine if the rotated crop would be injured by the residual pesticide residues.") (emphasis added). Those *human*

health standards have nothing to do with the issue here: whether diclosulam causes damage to crops.[22]

In fact, the evidence specifically confirmed that "Dow AgroSciences LLC had not submitted any target area phytotoxicity studies or data on peanuts treated with diclosulam" and that the "EPA did not require Dow AgroSciences LLC to submit data concerning target area phytotoxicity for peanuts." JA 216. As an EPA agent explained to petitioners' expert, "EPA did not evaluate whether diclosulam (Strongarm) had a toxic effect on peanut plants." *Id.*[23]

To be sure, EPA has generally reserved the right subsequently to request efficacy data, but the potential for a follow-up assessment in no way affects its initial, conditional registration of Strongarm without having decided whether target-area phytotoxicity might render Dow's effi-

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[22] Although both FIFRA and EPA regulations require the agency to "publish in the Federal Register . . . a notice of each application for registration of any pesticide if it contains any new active ingredient" and to provide for public "comment," § 136a(c)(4); *see* 40 C.F.R. §§ 152.102, 152.119, it apparently did not do so for Strongarm. The only public notice petitioners have been able to locate in the Federal Register lists Dow's petition to establish a food tolerance for diclosulam, but not its registration of Strongarm. *See* 63 Fed. Reg. 64,484, 64,488-89 (1998).

[23] In a carefully worded affidavit submitted by Dow employee Dr. John J. Jachetta, Dow did not dispute that omission. *See* JA 219-23. That affidavit does not claim that Dow submitted target-area phytotoxicity studies, but it does claim that Dow submitted "studies evaluating the effects of Strongarm on Seedling emergence and vegetative vigor of *non*-target terrestrial plants." JA 223 (emphasis added). Importantly, whatever plants were involved in those studies, Jachetta surely would have highlighted studies submitted by Dow to EPA that concerned potential damage to peanuts. The omission in his affidavit is glaring. In addition, Jachetta's RRI submission to EPA contains only a brief summary of efficacy studies. Those studies appear to be focused entirely on whether the product will control weeds – not target-area phytotoxicity. *See* J. Jachetta, *et al.*, *Reduced Risk Rationale for Diclosulam Herbicide Used in the Control of Broadleaf Weeds in Peanuts* 24 (1998). (Although no discovery has occurred in this case, petitioners obtained this document from EPA through the Freedom of Information Act. Petitioners will promptly lodge this material with the Court upon request.)

cacy claims "false or misleading" and its Strongarm product "misbranded." § 136(q)(1)(A); *see also* § 136a(c)(5). The Court in *Medtronic* similarly found no preemption even though the pacemaker approved under the FDA's substantial-equivalence procedure had a continuing duty to satisfy the FDA's standards pertaining to "labeling[] and the misbranding and adulteration provisions of the Act." *Medtronic*, 518 U.S. at 493 (quoting FDA letter).[24] As in *Medtronic*, so too here the farmers' claims are not preempted. Agency inaction – based on Congress's repeal of the statutory requirement that EPA verify efficacy claims before registering a pesticide – cannot preempt in this circumstance. *Sprietsma*, 537 U.S. at 64-65 (rejecting reliance on Coast Guard's decision "not to adopt a regulation requiring propeller guards on motorboats"); *Freightliner*, 514 U.S. at 286-87 (rejecting preemption where federal agency "did not decide that the minimum, objective safety standard required by [federal statute] should be the absence of all standards, both federal and state").

Interpreting § 136v(b) to preempt state-law damages actions challenging label claims regarding pesticide efficacy creates a dilemma for EPA unintended by Congress: to divert resources away from its primary mission of protecting human health and the natural environment to regulate pesticide efficacy or to let pesticide efficacy go unchecked knowing that States are preempted from filling this void. There is no evidence that, in enacting § 136a(c)(5) and § 136v(b), Congress intended to leave pesticide efficacy unmonitored by preempting state-law claims. Because Congress wanted EPA to devote its limited resources to public health and natural environment issues, FIFRA should not be interpreted as preempting state-law damages actions regarding pesticide efficacy.

[24] *Compare* 21 U.S.C. § 352(a) ("A drug or device shall be deemed to be misbranded . . . [i]f its labeling is false or misleading in any particular.") *with* 7 U.S.C. § 136(q)(1)(A) ("[a] pesticide is misbranded if . . . its labeling bears any statement . . . which is false or misleading in any particular").

The Court "should not impute to Congress a purpose to paralyze with one hand what it sought to promote with the other." *American Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 513 (1981) (internal quotation marks omitted).[25]

B. Petitioners' Claims Are Consistent With FIFRA's Misbranding Requirements

Even aside from EPA's waiver of review of efficacy claims, the farmers' claims are not preempted because they are completely consistent with FIFRA's prohibition on any distributed or sold pesticide that is "misbranded." § 136j(a)(1)(E). A pesticide is "misbranded" if its label is "false or misleading," contains inadequate "directions for use," or omits a necessary "warning or caution statement." § 136(q)(1)(A), (F), (G). State-law damages claims – even for failure to warn – would not impose a labeling or packaging requirement "in addition to or different from" those FIFRA misbranding prohibitions. § 136v(b). Instead, such claims would be consistent with the misbranding prohibitions by giving a remedy to injured farmers for the pesticide manufacturer's failure to ensure that its label is accurate, a requirement imposed by federal law.[26] To the ex-

[25] These are not simply theoretical concerns. DDT was banned ultimately because of its hazardous environmental consequences, but not until many years after the first lawsuits were filed asserting injuries from DDT. *See supra* p. 2. Other pesticides have been the cause of deaths to persons from acute pesticide poisoning. *See* H. Wellford, *Sowing the Wind* 219-28 (1972). It is thus perfectly logical for Congress to entrust to EPA the tasks of evaluating pesticides for those harms, while leaving to private remedial enforcement through common-law suits the types of crop damage caused by pesticides. Indeed, numerous provisions of FIFRA entrust EPA with responsibility to safeguard the environment and public health, a statutory directive in sharp contrast to Congress's mandate with respect to pesticide efficacy. *See, e.g.*, § 136a(c)(5)(C), (D) (EPA to approve pesticides that do not produce "unreasonable adverse effects on the environment").

[26] This Court need not determine that the farmers are asserting that Dow violated FIFRA in its various particulars to uphold their claims under this theory. Rather, it is sufficient that the farmers allege that Dow's label falsely warranted its product. Those claims are consistent with FIFRA's general prohibition on misbranding. *See Med-*

tent Dow's actions are inconsistent with the standards imposed by federal law, a state-law suit to remedy such injuries would not be preempted, as this Court held unanimously in *Medtronic* under a preemption provision that likewise applied to state requirements "different from, or in addition to," federal law. *See* 518 U.S. at 495; *id.* at 513 (O'Connor, J., concurring in relevant part).[27]

The absence of any state requirement at variance with a federal standard is made even clearer by the fact that EPA has not imposed a government-worded statement on the Strongarm label with which a state-law damages judgment might conflict. *Cf. id.* at 504 (Breyer, J., concurring in part and in the judgment) (concluding that a state-law requirement of a one-inch hearing-aid wire would be preempted if federal law required a two-inch wire). Rather, EPA permitted *Dow*'s proposed language, which claimed that "Use of Strongarm is recommended in all areas where peanuts are grown." JA 86, 108, 175. Neither FIFRA nor EPA "required" Dow to make or to prove that particular claim of efficacy. If Dow's claims of product efficacy were false, misleading, or otherwise misbranded as defined in FIFRA, then a state-law damages action relying on a parallel misbranding standard would be consistent with, and thus not "in addition to or different from," federal requirements. The mere fact that state-law claims require proof of additional elements (such as breach of a common

tronic, 518 U.S. at 495 (rejecting preemption in situation where "precise contours of [plaintiffs'] theory of recovery have not yet been defined" because "pre-emption issue was decided on the basis of the pleadings"). Petitioners will have ample time, and Dow sufficient notice, to litigate those claims as discovery proceeds.

[27] Indeed, the government recently endorsed this reasoning in a brief to this Court (which withdrew the positions it had advanced in the *Etcheverry* case), explaining that the Court's "unanimous[]" holding in *Medtronic* means that FIFRA "does not bar common law tort claims that are based on a violation of federal regulations – *i.e.*, where federal regulations furnish the standard of care." Amicus Br. for United States at 13, *American Cyanamid Co. v. Geye*, No. 02-367 (U.S. filed May 30, 2003) ("U.S. *Geye* Amicus Br.").

law duty) would not, in itself, impose a requirement different from FIFRA; the burden, after all, would be on the injured party and not the manufacturer to establish such proof. *See Medtronic*, 518 U.S. at 494; *id.* at 513 (O'Connor, J., concurring in relevant part) ("To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ.").

FIFRA also provides that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under [FIFRA]." § 136a(f)(2). If the mere fact that a pesticide has been registered is no defense to a misbranding charge by EPA, then there is no reason to find it a defense preempting a damages action.[28]

Enforcing a misbranding prohibition through state-law claims is also consistent with FIFRA's continuing duty on registrants to report adverse effects that may indicate the need for a change in the label. *See* 40 C.F.R. § 159.184 ("Toxic or Adverse Effect Incident Reports"); § 136d(b) (EPA may cancel registration "[i]f it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of [FIFRA]"). Accordingly, state-law damages actions support – not undermine – the federal mislabeling requirements. *See* U.S. Inv. Br. 4 ("EPA requires the registrant, after a pesticide has been registered, to report incidents of known harm to non-target organisms, such as crops, if the pesticide label does not provide adequate notice of the risk of such harm."). State-law claims provide a means for manufacturers to assess which incidents of pesticide harm merit reporting to EPA.

[28] In a state damages suit, the plaintiff bears the burden of persuasion, whereas in an EPA cancellation or suspension action the pesticide manufacturer "has a continuing burden of proof to establish that its product is entitled to registration." *Dow Chem. Co. v. Ruckelshaus*, 477 F.2d 1317, 1324 (8th Cir. 1973); *see* 40 C.F.R. § 164.80(b).

C. The Farmers' Claims Do Not Add "Different" Requirements Under § 136v(b)

Even if preemption were not avoided by EPA's waiver of efficacy review or the farmers' state-law claims imposing only parallel requirements to FIFRA, their suit still would not be barred. Proof of the elements of the farmers' claims does not impose requirements "in addition to or different from" FIFRA's labeling or packaging requirements.

1. The strict liability claims are not preempted

The farmers allege that Strongarm was at all relevant times within the exclusive control of Dow when it was "designed, formulated, developed, produced, manufactured and sold." JA 189. Dow therefore is liable for defective design in the rendering of an unreasonably dangerous product under state strict liability principles. The court below deemed that cause of action equivalent to a "failure to warn" claim subject to preemption. Pet. App. 19a. It reasoned that, to avoid future liability, a manufacturer would have to alter the label, an act the court presumed would be foreclosed under § 136v(b). *Id.*

The error in the court's analysis, however, is that breach of a duty – a "failure to warn" – is not dispositive in analyzing a strict liability claim. In fact, the elements of strict liability are a defective product that was unreasonably dangerous, the defect arose when the product was in the defendant's control, and injury to the plaintiff. *See Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 336-38 (Tex. 1998) (rejecting argument that fair warning can foreclose strict liability claim "as a matter of law"). Strict liability claims "mak[e] the seller subject to liability to the user or consumer *even though he has exercised all possible care in the preparation and sale of the product.*" *Restatement (Second) of Torts* § 402A cmt. a (1965) (emphasis added). Under Texas strict liability law, the warning contained on a label is at best a factor for the jury to consider, and not a dispositive consideration as a matter of law. *See Uniroyal*, 977 S.W.2d at 336 ("'[W]hen a safer design can reasonably be implemented and risks can reasonably be designed out of a product, adoption of the safer design is required over a warning that leaves a significant residuum of such risks. . . . Warnings are not . . . a substitute for the provision of a reasonably safe design.'") (quoting *Restatement (Third) of Torts: Product Liability* § 2, cmt. *l* (1998)) (emphasis omitted).

Moreover, in this case, Dow marketed Strongarm to west Texas farmers whose lands have a pH of 7.2 or higher. *See* JA 125, 179. Dow has now admitted in its supplemental label that Strongarm is *never* safe to use in such soils. *See* JA 181 ("Do not apply Strongarm to soils with a pH of 7.2 or greater."). This is not a case, therefore, where a label warning could ever make the product safe for use on farms with high pH soil. Because only a redesign of the product could do so, the farmers' claims are completely unaffected by any type of failure to warn theory. It is illogical for Dow to contend that it may market an unreasonably dangerous product and then claim preemption because a label warning could have said not to use the product at all. Indeed, the result of a damages action confirming what Dow has now admitted – that Strongarm can *never* be used in soils with a pH of 7.2 or greater and that *no* label warning could render it safe for use there – would at most have only the indirect effect of banning or restricting the use of the pesticide in those areas, which is precisely the type of direct authority § 136v(a) preserves for States.

Even in reversing its position on FIFRA preemption, the U.S. acknowledges that strict liability claims should survive. *See* U.S. *Geye* Amicus Br. at 13 ("[A] claim based on strict liability . . . need not be based on statements in labeling at all."). Because a strict liability claim does not contain as an element any breach of duty or failure to warn on the manufacturer's part, common-law liability for such a claim cannot impose a "requirement" with respect

to labeling.[29] Such claims were routinely upheld against pesticide manufacturers before and after the 1972 Act.[30] The same result should govern now.

2. The express warranty claims are not preempted

The farmers allege breach of warranty (including claims under the Texas DTPA, which "establishes a remedy for the breach of an independent warranty," Pet. App. 17a) based on express warranties provided by Dow (1) on the label and (2) off the label and before the sale. *See* JA 185-89. Those warranty theories are not preempted, however, because FIFRA imposes no "requirements" with respect to

[29] Contributory negligence thus ordinarily is not a defense to a strict liability claim, except when the injured party "discovers the defect and is aware of the danger" and nonetheless "proceeds unreasonably to make use of the product and is injured by it." *Restatement (Second)* § 402A cmt. n. The dramatic changes in the Strongarm label in 2001 all but concede that the product was not suited for use on petitioners' farms, *see supra* pp. 11-12, so the 2000 label could not have given the farmers the requisite notice that would establish contributory negligence. The farmers also allege strict liability under *Restatement (Second)* § 402B, which provides strict liability when the seller of chattels makes "a misrepresentation of a material fact concerning the character or quality of a chattel sold by him" that causes injury, even in the absence of a fraudulent or negligent statement. *See* JA 189.

[30] *See, e.g., Streich v. Hilton-Davis*, 692 P.2d 440 (Mont. 1984) (sufficient evidence to hold potato sprout suppressant manufacturer liable for negligence, breach of implied warranty, and strict liability for failure to warn of side effects harmful to potato crop); *Mortensen v. Chevron Chem. Co.*, 693 P.2d 1038 (Idaho 1984) (affirming JNOV for fungicide manufacturer against strict liability claim by buyer that chemical damaged seed potatoes because no proof that product was defective); *Shields v. Morton Chem. Co.*, 518 P.2d 857 (Idaho 1974) (reversing judgment for manufacturer of pesticide-fungicide for breach of warranty and strict liability because trial judge wrongly instructed jury that contributory negligence applied to both counts, when it applies only to negligence); *Rose v. Buffalo Air Serv.*, 104 N.W.2d 431 (Neb. 1960) (chemical company strictly liable for mispackaging chemicals to be sprayed on crops); *Chapman Chem. Co. v. Taylor*, 222 S.W.2d 820 (Ark. 1949) (manufacturer held strictly liable for breaching duty to test for crop damage caused by extrahazardous chemical).

express warranties. But, having made such warranties, Dow was obliged to make them true.

First, the label expressly provides that "Dow AgroSciences *warrants* that this product . . . is reasonably fit for the purposes stated on the label." JA 111 (emphasis added); *see also* JA 111-12. Indeed, Dow admitted, and the district court held, that "Strongarm's label provisions . . . provided a limited express warranty." CA App. 313; Pet. App. 26a n.1; *see also* JA 208. The "purposes" to which Dow's express warranty refers include the label representation that the "[u]se of Strongarm is recommended in *all* areas where peanuts are grown." JA 108, 175 (emphasis added). *Second*, the farmers relied on off-label representations made prior to their purchase of Strongarm by Dow's agents, who trumpeted that Strongarm was reasonably fit for use on peanuts and would yield "excellent" results in west Texas soil.[31] Under neither theory are the farmers' claims preempted.

a. The court based its conclusion that the on-label express warranty claim was preempted on the ground that the farmers' success in a damages suit "would provide a manufacturer with a strong incentive to alter its label to avoid future liability." Pet. App. 16a. That conclusion went beyond the far more limited text of § 136v(b), which preempts only state-law "requirements" that differ from or add to FIFRA "requirements" – but not claims that might induce a pesticide manufacturer to alter its product label.

As the *Cipollone* plurality instructed, the court should instead have assessed whether the "legal duty that is the predicate of the common-law damages action constitutes a [state-law] 'requirement'" under the preemption provision. 505 U.S. at 523-24. Because "[a] manufacturer's liability

[31] The evidence on this point is developed as to some of the farmers through affidavits. *See* JA 147-48, 152-53, 157-58. The absence of evidence as to other farmers at this early stage of the litigation (prior to full discovery) should not foreclose other petitioners on remand from advancing claims based on this theory of liability.

for breach of an express warranty derives from, and is measured by, the terms of that warranty . . . , the 'requirements' imposed by an express warranty claim are not 'imposed under State law,' but rather imposed *by the warrantor*" and thus are not preempted. *Id.* at 525 (alteration omitted); *see also id.* at 525 n.23 ("express warranty claims . . . sound in contract rather than in tort").

Under that analysis, the on-label, express warranty claims are not preempted "labeling requirements" because they are not imposed under state law. Instead, they derive solely from Dow, the warrantor. *See id.* at 526 ("That the terms of the warranty may have been set forth in advertisements rather than in separate documents is irrelevant to the pre-emption issue . . . because, although the breach of warranty claim is made 'with respect to advertising,' it does not rest on a duty imposed by state law.") (alteration omitted); *see American Airlines, Inc. v. Wolens*, 513 U.S. 219, 228 (1995) (breach of contract suit not preempted by Airline Deregulation Act because "terms and conditions airlines offer and passengers accept are privately ordered obligations") (citing *Cipollone*, 505 U.S. at 526 (plurality op.)). Because nothing in FIFRA required Dow expressly to "warrant[]" that Strongarm "is reasonably fit for the purposes stated on the label" (JA 111), it is legally irrelevant that Dow felt "induce[d]" (Pet. App. 17a) to change its label to remove that warranty.

b. The Fifth Circuit also erred in holding that Dow's pre-sale, off-label statements promising the farmers "excellent" results in west Texas soils are preempted because they did not "deviate[]" from Dow's label claim that Strong-arm was "recommended in all areas where peanuts are grown" (JA 108, 175). *See* Pet. App. 17a. If those oral representations by Dow's agents merely reflect the label contents, then they should be enforceable just like the on-label warranty voluntarily provided by Dow. In any case, whether or not the off-label statements differed from the label, claims that those representations are false would

not be preempted because § 136v(b) does not preempt *any* off-label representations.[32]

Even assuming § 136v(b) could be read to preempt off-label claims that are similar to on-label claims, the pre-sale, off-label representations here were substantially different. While the label "recommended" Strongarm for use in "all" areas, the pre-sale, field-day representations were far more specific: they promised that Strongarm was "excellent" for use in "west Texas" soils. JA 147, 152, 190-91. Plainly, the farmers were interested in knowing whether Strongarm would be effective on their own lands, and that is the assurance they received from Dow, whose agents claimed that Strongarm was not merely recommended but would be "excellent" for their west Texas peanut crops. To be sure, the geography covered by the original label is broad enough to cover west Texas, but any farmer would know that soil, climate, and other essential farming conditions will vary by geography. (Indeed, that is borne out here by Dow's subsequent action: within months of the farmers' disastrous experience, Dow sought EPA approval to alter the label to exclude or substantially limit use in the areas in which Dow had once claimed Strongarm would yield "excellent" results.[33])

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[32] Even the federal government appears to accept this argument for non-preemption. In *Geye*, the government noted that "[m]agazine advertisements, as well as many types of brochures, are not within FIFRA's express definition of 'labeling.'" U.S. *Geye* Amicus Br. at 11. The government then notes that any evidence based on such off-label statements would not be preempted and would be admissible to establish liability for non-preempted claims. *See id.* at 11-12. Thus, to the extent the farmers' claims stem from off-label statements – which they undisputedly do (JA 190) – FIFRA does not preempt them even under the government's revised position.

[33] In the court below, Dow asserted (using a thesaurus) that the words "excellent" and "recommend" were synonymous. Appellee's Br. 36-37. There is no merit to that position. An "excellent" product is one that "excel[s] or exceed[s] in kind or degree," or is "meritoriously near the standard or model." *Webster's Third New International Dictionary* 791 (2002). By contrast, to "recommend" is to "praise" or "to mention

3. The fraud claims are not preempted

The farmers' fraud claims are based on the same types of representations as their express warranty claims, and are backed by the allegation and evidence that Dow marketed Strongarm to the farmers and recommended it for "all" areas despite having knowledge that scientific studies had shown diclosulam to be toxic to peanuts grown in the high pH soils commonly found in Texas, New Mexico, and Oklahoma. *See supra* pp. 8-9. As with the express warranty claims, the court below erred in holding the pre-sale representation claims preempted. *See* Pet. App. 16a-17a.

The court's overbroad focus trained only on whether success would "provide a manufacturer with a strong incentive" to alter its label "to avoid future liability." *Id.* at 16a. The court failed to assess the source of the legal duty for fraud, which *Cipollone* makes clear has nothing to do with labeling, but rests "on a more general obligation – the duty not to deceive." 505 U.S. at 528-29 (plurality op.). The *Cipollone* plurality found that fraud claims based on statements made in advertising were not preempted, even though the 1969 Public Health Cigarette Smoking Act prohibited state-law "requirement[s]" "with respect to . . . advertising." *Id.* at 515. "Unlike state-law obligations concerning the warnings necessary to render a product 'reasonably safe,' state-law proscriptions on intentional fraud rely only on a single, uniform standard: falsity." *Id.* at 529.

That analysis compels the conclusion that the farmers' fraud claims here, whether based on on-label or off-label representations, are not preempted. Indeed, the farmers' claim that Dow knew diclosulam was inappropriate for use in high pH soils is indistinguishable from the claim that

or introduce as being worthy of acceptance, use, or trial." *Id.* at 1897. Dow's oral representations therefore greatly exceeded the "praise" offered on its label. Accordingly, holding Dow liable for those oral representations in no way would be "in addition to or different from" any labeling "requirements."

Cipollone held was not preempted, which alleged that cigarette manufacturers "possessed[] but had ignored and failed to act upon medical[] and scientific data indicating that cigarettes were hazardous to the health of consumers." *Id.* at 510 (internal quotation marks omitted). *See also Nelson v. Najm*, 127 S.W.3d 170, 175-76 (Tex. App. 2003) (warranty or "as is" provision invalid to negate fraud claim based on concealment of "a known fact").[34]

4. The negligence claims are not preempted

The farmers assert claims for negligence in the "development, testing, manufacture, production and promotion of Strongarm." JA 185. Because their theories concern the formulation and promotion of Strongarm, there is no conflicting FIFRA requirement. The Fifth Circuit's rationale for holding this claim preempted was that it is "simply a disguised claim for failure to warn." Pet. App. 19a. But because Dow's inducement to change its label can address only one theory for negligence – a breach of duty to promote accurately its products – there is no basis for preempting the farmers' claims for negligent testing, development, and manufacture of Strongarm as imposing a requirement in addition to or different from the label. *See, e.g., Quest Chem. Corp. v. Elam*, 898 S.W.2d 819, 820-21 (Tex. 1995) (per curiam) (noting that claims against pesticide manufacturer for negligent testing, manufacturing, and formulating should "escape FIFRA preemption" under Texas law because those claims are not based on

[34] Although Dow claimed below that the label's limitation of remedies provision would in any case limit recovery to replacement of the product or refund of the purchase price, it is black-letter law that public policy prevents a manufacturer from limiting its liability for its own fraud. *See Helena Chem. Co. v. Wilkins*, 47 S.W.3d 486, 505 (Tex. 2001) ("Helena's liability-limitation clauses cannot preclude the Wilkinses' lost-profit recovery for nonwarranty representations or unconscionability."); *Western Union Tel. Co. v. Edsall*, 63 Tex. 668, 1885 WL 7106, at *5 (1885) (enforcing limitation of liability clause on back of telegraph form only "in the absence of fraud").

"alleged failure to provide adequate warnings and instructions" on the label).

Moreover, as with the strict liability claims, because Dow admits that Strongarm is *never* safe to use in soils with a pH of 7.2 or greater, the negligence claims cannot be negated by a defense of inadequate warning that, when followed, would make the product safe for use. *See Cipollone*, 505 U.S. at 524-25 (plurality op.) (no preemption of "claims that rely solely on [maker's] testing or research practices or other actions unrelated to advertising or promotion"). And, because § 136v(a) empowers States directly to restrict pesticide sale or use, a damages suit that indirectly does so should not be preempted even if it might induce a label alteration. Section 136v(b) should not be read to undercut a State's express authority under § 136v(a), especially in areas traditionally regulated by States such as agriculture and consumer protection.

This is a classic case of inadequate testing, as evidenced by Dow's subsequent amendment to its Strongarm label to provide special instructions for use (or to prohibit use altogether) in Texas, New Mexico, and Oklahoma. Dow's theory of FIFRA would allow it to use the unfortunate farmers – to whom Dow marketed its new product directly with great fanfare at the Field Days – to perform its field testing, with little if any responsibility for the devastating consequences (including, for some, bankruptcy). The contrary decision of the court below creates a classic Catch 22. The label says on its face that it is "registered" with EPA and that its "approved uses" include "all areas where peanuts are grown." JA 107-08, 175. Thus, a farmer reasonably must rely on the EPA-approved pesticide label to obtain the product because without EPA approval the product cannot be sold. But, if he relies on the label's assurance that the product will work, then the law tells him, in effect, that he was crazy to have done so.

III. CLAIMS CHALLENGING POST-USE, OFF-LABEL STATEMENTS ARE NOT PREEMPTED

A last set of claims concerns representations by Dow after Strongarm had been used. *See* JA 190-91. Specifically, the farmers alleged that Dow had committed fraud, fraudulent inducement to contract, and breach of express warranty by promising to compensate the farmers for any damages they sustained from using Strongarm. They also contended that those post-use statements estopped Dow from claiming label defenses. *See id.* The Fifth Circuit erred in holding that the farmers' claims stemming from Dow's post-use representations are preempted. Pet. App. 16a-17a, 20a (fraud claims preempted).

The district court found that "FIFRA does not preempt these claims" because the "off-label remarks do not repeat any information found on the Strongarm label." Pet. App. 29a; *cf. Cipollone*, 505 U.S. at 525-26 (plurality op.) (If "a manufacturer expressly promised to pay a smoker's medical bills if she contracted emphysema, the duty to honor that promise could not fairly be said to be 'imposed under state law,' but rather is best understood as undertaken by the manufacturer itself.").[35] That conclusion was plainly correct, but the Fifth Circuit's overbroad opinion holds that "the farmers' claims for breach of warranty, fraud, DTPA, defective design and negligence are *all* preempted."

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[35] The district court subsequently has treated the court of appeals' judgment as affirming the dismissal of *all* of petitioners' claims on preemption grounds. Over the farmers' objection, the court returned all funds paid into the court's registry by Dow for damages resulting from, *inter alia*, its post-use representations, on the basis that petitioners had no more live claims for which a deposit would be warranted. *See* JA 226-27. This Court therefore should hold that the farmers' post-use claims also are not preempted, and permit the parties to litigate what effect, if any, the label's limitation of remedies provision has on those claims. The Fifth Circuit's suggestion that the farmers did not seek appellate review of the district court's determination on that point, *see* Pet. App. 17a n.15, is plainly contradicted by the farmers' opening brief below. *See* Appellants' Br. 51-55; Appellee's Br. 57-62; *see also supra* n.34 (purported limitation of liability for fraud is void).

Pet. App. 20a (emphasis added). The court based that view on the ground that "success on such claims would necessarily induce Dow to alter its product label." *Id.*

The court's holding is clearly erroneous. The farmers had used Strongarm and were relying on post-use representations that Dow would remedy their injuries from that use. Such theories of fraud, fraud in the inducement, warranty, estoppel, and waiver have nothing to do with the label. Whether Dow experiences any "induce[ment]" to change the label as a result of its post-use representations to the farmers stems not from any FIFRA requirements – which are completely silent on the question of what a manufacturer's legal responsibilities are to its consumers once its product is used – but rather from the self-interest of the manufacturer. This Court has never sanctioned preemption on the theory that a private-party manufacturer can exonerate itself from common-law liability by its voluntary actions not compelled by federal law.

CONCLUSION

The court of appeals' judgment should be reversed.

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ADDENDUM
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Federal Insecticide, Fungicide, and Rodenticide Act, ch. 125, 61 Stat. 163 (1947), as amended by the Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, § 2, 86 Stat. 973 (codified at 7 U.S.C. §§ 136 *et seq.*):

7 U.S.C. § 136 (excerpted) 1a
7 U.S.C. § 136a 5a
7 U.S.C. § 136j 38a
7 U.S.C. § 136v 43a
7 U.S.C. § 136w-1 ..... 45a
7 U.S.C. § 136w-2 ..... 47a
7 U.S.C. § 136w-5 ..... 48a

Federal Insecticide, Fungicide, and Rodenticide Act § 3(c)(5), as added by the Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, § 2, 86 Stat. 979-81 (codified at 7 U.S.C. § 136a(c)(5) (1976)) 49a

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40 C.F.R. § 152.50 ..... 50a
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40 C.F.R. § 152.113 ..... 56a
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7 U.S.C. § 136. Definitions

For purposes of this subchapter –

* * * * *

(p) Label and labeling

(1) Label

The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) Labeling

The term "labeling" means all labels and all other written, printed, or graphic matter–

(A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

(q) Misbranded

(1) A pesticide is misbranded if–

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;

(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

(D) its label does not bear the registration number assigned under section 136e of this title to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment; or

(H) in the case of a pesticide not registered in accordance with section 136a of this title and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: "Not Registered for Use in the United States of America".

(2) A pesticide is misbranded if–

(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if

there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions or purchase, except that a pesticide is not misbranded under this subparagraph if–

(i) The size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

(ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;

(B) the labeling does not contain a statement of the use classification under which the product is registered;

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing–

(i) the name and address of the producer, registrant, or person for whom produced;

(ii) the name, brand, or trademark under which the pesticide is sold;

(iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and

(iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification; and

(D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this subchapter–

(i) the skull and crossbones;

(ii) the word "poison" prominently in red on a background of distinctly contrasting color; and

(iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide.

* * * * *

7 U.S.C. § 136a. Registration of Pesticides

(a) Requirement of registration

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

(b) Exemptions

A pesticide which is not registered with the Administrator may be transferred if–

(1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or

(2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

(c) Procedure for registration

(1) Statement required

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes–

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

(D) the complete formula of the pesticide;

(E) a request that the pesticide be classified for general use or for restricted use, or for both; and

(F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) With respect to pesticides containing active ingredients that are initially registered under this subchapter after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide, except that such permission shall not be required in the case of defensive data.

(ii) The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after August 3, 1996, and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that–

(I) there are insufficient efficacious alternative registered pesticides available for the use;

(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;

(III) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this clause 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

(iii) Except as otherwise provided in clause (i), with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of de-

livery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the

application. Notwithstanding any other provision of this subchapter, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation.

(iv) After expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under clauses (i), (ii), and (iii), the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data.

(v) The period of exclusive use provided under clause (ii) shall not take effect until 1 year after August 3, 1996, except where an applicant or registrant is applying for the registration of a pesticide containing an active ingredient not previously registered.

(vi) With respect to data submitted after August 3, 1996, by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, if such data relates solely to a minor use of a pesticide, such data shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of such data. The applicant or registrant at the time the new minor use is requested shall notify the Administrator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provisions of this paragraph. If the minor use registration which is supported by data submitted pursuant to this subsection is voluntarily canceled or if such data are subsequently used to support a nonminor use, the data shall no longer be subject to the exclusive use provisions of this clause but shall instead be considered by the Administrator in accordance with the provisions of clause (i), as appropriate.

(G) If the applicant is requesting that the registration or amendment to the registration of a pesticide be expedited, an explanation of the basis for the request must be submitted, in accordance with paragraph (10) of this subsection.

(2) Data in support of registration

(A) In general

The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter the Administrator requires any additional kind of information under subparagraph (B) of this paragraph,

the Administrator shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, the public health and agricultural need for such minor use, and the level and degree of potential beneficial or adverse effects on man and the environment. The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor agricultural use under this subchapter, any field residue data from a geographic area where the pesticide will not be registered for such use. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 136h of this title, within 30 days after the Administrator registers a pesticide under this subchapter the Administrator shall make available to the public the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the Administrator's decision.

(B) Additional data

(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure

the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing, data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance

with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iv) Notwithstanding any other provision of this subchapter, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 136d(d) of this title. The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is con-

sistent with this subchapter. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this subchapter, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of paragraph (1)(D). Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data.

(vi) Upon the request of a registrant the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under section 136a-1 of this title for the other uses of the pesticide established as of August 3, 1996, if–

(I) the data to support other uses of the pesticide on a food are being provided;

(II) the registrant, in submitting a request for such an extension, provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(III) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under section 136a-1 of this title; and

(IV) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this clause, the Administrator may take action to modify or revoke the extension under this clause if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide, in writing to the registrant, a notice revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date established by the Administrator for the submission of the data.

(vii) If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the regis-

trant, shall not take any action pursuant to this clause in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under section 136a-1 of this title for the supported uses identified pursuant to this clause unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of this subparagraph regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding the provisions of this clause, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish

a new effective date by which the minor use shall be deleted from the registration.

(viii)(I) If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regulatory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by multiple requirements on the registrant.

(II) The Administrator may enter into a cooperative agreement with a State to carry out subclause (I).

(III) Not later than 1 year after August 3, 1996, the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements.

(C) Simplified procedures

Within nine months after September 30, 1978, the Administrator shall, by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

(D) Exemption

No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to–

(i) submit or cite data pertaining to such purchased product; or

(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

(E) Minor use waiver

In handling the registration of a pesticide for a minor use, the Administrator may waive otherwise applicable data requirements if the Administrator determines that the absence of such data will not prevent the Administrator from determining–

(i) the incremental risk presented by the minor use of the pesticide; and

(ii) that such risk, if any, would not be an unreasonable adverse effect on the environment.

(3) Time for acting with respect to application

(A) In general

The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify the applicant of the Administrator's determination that it does not comply with the provisions of the subchapter in accordance with paragraph (6).

(B) Identical or substantially similar

(i) The Administrator shall, as expeditiously as possible, review and act on any application received by the Administrator that–

(I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; or

(II) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data.

(ii) In expediting the review of an application for an action described in clause (i), the Administrator shall–

(I) within 45 days after receiving the application, notify the registrant whether or not the application is complete and, if the application is found to be incomplete, reject the application;

(II) within 90 days after receiving a complete application, notify the registrant if the application has been granted or denied; and

(III) if the application is denied, notify the registrant in writing of the specific reasons for the denial of the application.

(C) Minor use registration

(i) The Administrator shall, as expeditiously as possible, review and act on any complete application–

(I) that proposes the initial registration of a new pesticide active ingredient if the active ingredient is proposed to be registered solely for minor uses, or proposes a registration amendment solely for minor uses to an existing registration; or

(II) for a registration or a registration amendment that proposes significant minor uses.

(ii) For the purposes of clause (i)–

(I) the term "as expeditiously as possible" means that the Administrator shall, to the greatest extent practicable, complete a review and evaluation of all data, submitted with a complete application, within 12 months after the submission of the complete application, and the failure of the Administrator to complete such a review and evaluation under clause (i) shall not be subject to judicial review; and

(II) the term "significant minor uses" means 3 or more minor uses proposed for every nonminor use, a minor use that would, in the judgment of the Ad-

ministrator, serve as a replacement for any use which has been canceled in the 5 years preceding the receipt of the application, or a minor use that in the opinion of the Administrator would avoid the reissuance of an emergency exemption under section 136p of this title for that minor use.

(D) Adequate time for submission of minor use data

If a registrant makes a request for a minor use waiver, regarding data required by the Administrator, pursuant to paragraph (2)(E), and if the Administrator denies in whole or in part such data waiver request, the registrant shall have a full-time period for providing such data. For purposes of this subparagraph, the term "full-time period" means the time period originally established by the Administrator for submission of such data, beginning with the date of receipt by the registrant of the Administrator's notice of denial.

(4) Notice of application

The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

(5) Approval of registration

The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d) of this section–

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this subchapter;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

(6) Denial of registration

If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, the Administrator shall notify the applicant for registration of the Administrator's determination and of the Administrator's reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, the Administrator shall notify the applicant of the Administrator's decision and of the Administrator's rea-

sons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 136d of this title.

(7) Registration under special circumstances

Notwithstanding the provisions of paragraph (5)–

(A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provisions of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations issued under this subchapter, and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(C) The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and

submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this subchapter, and on such other conditions as the Administrator may prescribe. A conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

(8) Interim administrative review

Notwithstanding any other provision of this subchapter, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this subchapter, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. Notice of the definition of the terms "validated test" and "other significant evidence" as used herein shall be published by the Administrator in the Federal Register.

(9) Labeling

(A) Additional statements

Subject to subparagraphs (B) and (C), it shall not be a violation of this subchapter for a registrant to modify the labeling of an antimicrobial pesticide product to include relevant information on product efficacy, product composition, container composition or

design, or other characteristics that do not relate to any pesticidal claim or pesticidal activity.

(B) Requirements

Proposed labeling information under subparagraph (A) shall not be false or misleading, shall not conflict with or detract from any statement required by law or the Administrator as a condition of registration, and shall be substantiated on the request of the Administrator.

(C) Notification and disapproval

(i) Notification

A registration may be modified under subparagraph (A) if–

(I) the registrant notifies the Administrator in writing not later than 60 days prior to distribution or sale of a product bearing the modified labeling; and

(II) the Administrator does not disapprove of them modification under clause (ii).

(ii) Disapproval

Not later than 30 days after receipt of a notification under clause (i), the Administrator may disapprove the modification by sending the registrant notification in writing stating that the proposed language is not acceptable and stating the reasons why the Administrator finds the proposed modification unacceptable.

(iii) Restriction on sale

A registrant may not sell or distribute a product bearing a disapproved modification.

(iv) Objection

A registrant may file an objection in writing to a disapproval under clause (ii) not later than 30 days after receipt of notification of the disapproval.

(v) Final action

A decision by the Administrator following receipt and consideration of an objection filed under clause (iv) shall be considered a final agency action.

(D) Use dilution

The label or labeling required under this subchapter for an antimicrobial pesticide that is or may be diluted for use may have a different statement of caution or protective measures for use of the recommended diluted solution of the pesticide than for use of a concentrate of the pesticide if the Administrator determines that–

(i) adequate data have been submitted to support the statement proposed for the diluted solution uses; and

(ii) the label or labeling provides adequate protection for exposure to the diluted solution of the pesticide.

(10) Expedited registration of pesticides

(A) Not later than 1 year after August 3, 1996, the Administrator shall, utilizing public comment, develop procedures and guidelines, and expedite the review of an application for registration of a pesticide or an amendment to a registration that satisfies such guidelines.

(B) Any application for registration or an amendment, including biological and conventional pesticides, will be considered for expedited review under this paragraph. An application for registration or an amendment shall qualify for expedited review if use of the pesticide proposed by the application may reasonably be expected to accomplish 1 or more of the following:

(i) Reduce the risks of pesticides to human health.

(ii) Reduce the risks of pesticides to nontarget organisms.

(iii) Reduce the potential for contamination of groundwater, surface water, or other valued environmental resources.

(iv) Broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective.

(C) The Administrator, not later than 30 days after receipt of an application for expedited review, shall notify the applicant whether the application is complete. If it is found to be incomplete, the Administrator may either reject the request for expedited review or ask the applicant for additional information to satisfy the guidelines developed under subparagraph (A).

(d) Classification of pesticides

(1) Classification for general use, restricted use, or both

(A) As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use. If the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, the Administrator shall classify it for both general use and restricted use. Pesticide uses may be classified by regulation on the initial classification, and registered pesticides may be classified prior to reregistration. If some of the uses of the pesticide are classified for general use, and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses. The Administrator may require that its packaging and labeling for restricted uses shall be clearly

distinguishable from its packaging and labeling for general uses.

(B) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment, the Administrator will classify the pesticide, or the particular use or uses of the pesticide to which the determination applies, for general use.

(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, the Administrator shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use:

(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.

(ii) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.

(2) Change in classification

If the Administrator determines that a change in the classification of any use of a pesticide from general use to restricted use is necessary to prevent unreasonable adverse effects on the environment, the Administrator shall notify the registrant of such pesticide of such determination at least forty-five days before making the change and shall publish the proposed change in the Federal Register. The registrant, or other interested person with the concurrence of the registrant, may seek relief from such determination under section 136d(b) of this title.

(3) Change in classification from restricted use to General use

The registrant of any pesticide with one or more uses classified for restricted use may petition the Administrator to change any such classification from restricted to general use. Such petition shall set out the basis for the registrant's position that restricted use classification is unnecessary because classification of the pesticide for general use would not cause unreasonable adverse effects on the environment. The Administrator, within sixty days after receiving such petition, shall notify the registrant whether the petition has been granted or denied. Any denial shall contain an explanation therefor and any such denial shall be subject to judicial review under section 136n of this title.

(e) Products with same formulation and claims

Products which have the same formulation, are manufactured by the same person, the labeling of which contains the same claims, and the labels of which bear a designation identifying the product as the same pesticide may be registered as a single pesticide; and additional names and labels shall be added to the registration by supplemental statements.

(f) Miscellaneous

(1) Effect of change of labeling or formulation

If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this subchapter.

(2) Registration not a defense

In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter.

(3) Authority to consult other Federal agencies

In connection with consideration of any registration or application for registration under this section, the Administrator may consult with any other Federal agency.

(4) Mixtures of nitrogen stabilizers and fertilizer products

Any mixture or other combination of–

(A) 1 or more nitrogen stabilizers registered under this subchapter; and

(B) 1 or more fertilizer products,

shall not be subject to the provisions of this section or sections 136a-1, 136c, 136e, 136m, and 136o(a)(2) of this title if the mixture or other combination is accompanied by the labeling required under this subchapter for the nitrogen stabilizer contained in the mixture or other combination, the mixture or combination is mixed or combined in accordance with such labeling, and the mixture or combination does not contain any active ingredient other than the nitrogen stabilizer.

(g) Registration review

(1) General rule

(A) Periodic review

The registrations of pesticides are to be periodically reviewed. The Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations. The goal of these regulations shall be a review of a pesticide's registration every 15 years. No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 136d of this title.

(B) Limitation

Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide pursuant to this subchapter.

(2) Data

(A) Submission required

The Administrator shall use the authority in subsection (c)(2)(B) of this section to require the submission of data when such data are necessary for a registration review.

(B) Data submission, compensation, and exemption

For purposes of this subsection, the provisions of subsections (c)(1), (c)(2)(B), and (c)(2)(D) of this sec-

tion shall be utilized for and be applicable to any data required for registration review.

(h) Registration requirements for antimicrobial pesticides

(1) Evaluation of process

To the maximum extent practicable consistent with the degrees of risk presented by an antimicrobial pesticide and the type of review appropriate to evaluate the risks, the Administrator shall identify and evaluate reforms to the antimicrobial registration process that would reduce review periods existing as of August 3, 1996, for antimicrobial pesticide product registration applications and applications for amended registration of antimicrobial pesticide products, including–

(A) new antimicrobial active ingredients;

(B) new antimicrobial end-use products;

(C) substantially similar or identical antimicrobial pesticides; and

(D) amendments to antimicrobial pesticide registrations.

(2) Review time period reduction goal

Each reform identified under paragraph (1) shall be designed to achieve the goal of reducing the review period following submission of a complete application, consistent with the degree of risk, to a period of not more than–

(A) 540 days for a new antimicrobial active ingredient pesticide registration;

(B) 270 days for a new antimicrobial use of a registered active ingredient;

(C) 120 days for any other new antimicrobial product;

(D) 90 days for a substantially similar or identical antimicrobial product;

(E) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(F) 90 to 180 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this paragraph.

(3) Implementation

(A) Proposed rulemaking

(i) Issuance

Not later than 270 days after August 3, 1996, the Administrator shall publish in the Federal Register proposed regulations to accelerate and improve the review of antimicrobial pesticide products designed to implement, to the extent practicable, the goals set forth in paragraph (2).

(ii) Requirements

Proposed regulations issued under clause (i) shall–

(I) define the various classes of antimicrobial use patterns, including household, industrial, and institutional disinfectants and sanitizing pesticides, preservatives, water treatment, and pulp and paper mill additives, and other such products intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime;

(II) differentiate the types of review undertaken for antimicrobial pesticides;

(III) conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides and the function of review under this subchapter, considering the use patterns of the product, toxicity, expected exposure, and product type;

(IV) ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each type of label claim made; and

(V) implement effective and reliable deadlines for process management.

(iii) Comments

In developing the proposed regulations, the Administrator shall solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process.

(B) Final regulations

(i) Issuance

The Administrator shall issue final regulations not later than 240 days after the close of the comment period for the proposed regulations.

(ii) Failure to meet goal

If a goal described in paragraph (2) is not met by the final regulations, the Administrator shall identify the goal, explain why the goal was not attained, describe the element of the regulations included instead, and identify future steps to attain the goal.

(iii) Requirements

In issuing final regulations, the Administrator shall–

(I) consider the establishment of a certification process for regulatory actions involving risks that can be responsibly managed, consistent with the degree of risk, in the most cost-efficient manner;

(II) consider the establishment of a certification process by approved laboratories as an adjunct to the review process;

(III) use all appropriate and cost-effective review mechanisms, including–

(aa) expanded use of notification and non-notification procedures;

(bb) revised procedures for application review; and

(cc) allocation of appropriate resources to ensure streamlined management of antimicrobial pesticide registrations; and

(IV) clarify criteria for determination of the completeness of an application.

(C) Expedited review

This subsection does not affect the requirements or extend the deadlines or review periods contained in subsection (c)(3) of this section.

(D) Alternative review periods

If the final regulations to carry out this paragraph are not effective 630 days after August 3, 1996, until the final regulations become effective, the review period, beginning on the date of receipt by the Agency of a complete application, shall be–

(i) 2 years for a new antimicrobial active ingredient pesticide registration;

(ii) 1 year for a new antimicrobial use of a registered active ingredient;

(iii) 180 days for any other new antimicrobial product;

(iv) 90 days for a substantially similar or identical antimicrobial product;

(v) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(vi) 240 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this subparagraph.

(E) Wood preservatives

An application for the registration, or for an amendment to the registration, of a wood preservative product for which a claim of pesticidal activity listed in section 136(mm) of this title is made (regardless of any other pesticidal claim that is made with respect to the product) shall be reviewed by the Administrator within the same period as that established under this paragraph for an antimicrobial pesticide product application, consistent with the degree of risk posed by the use of the wood preservative product, if the application requires the applicant to satisfy the same data requirements as are required to support an application for a wood preservative product that is an antimicrobial pesticide.

(F) Notification

(i) In general

Subject to clause (iii), the Administrator shall notify an applicant whether an application has been granted or denied not later than the final day of the appropriate review period under this paragraph, unless the applicant and the Administrator agree to a later date.

(ii) Final decision

If the Administrator fails to notify an applicant within the period of time required under clause (i), the failure shall be considered an agency action unlawfully withheld or unreasonably delayed for purposes of judicial review under chapter 7 of title 5.

(iii) Exemption

This subparagraph does not apply to an application for an antimicrobial pesticide that is filed under subsection (c)(3)(B) of this section prior to 90 days after August 3, 1996.

(4) Annual report

(A) Submission

Beginning on August 3, 1996, and ending on the date that the goals under paragraph (2) are achieved, the Administrator shall, not later than March 1 of each year, prepare and submit an annual report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(B) Requirements

A report submitted under subparagraph (A) shall include a description of–

(i) measures taken to reduce the backlog of pending registration applications;

(ii) progress toward achieving reforms under this subsection; and

(iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations.

7 U.S.C. § 136j. Unlawful acts

(a) In general

(1) Except as provided by subsection (b) of this section, it shall be unlawful for any person in any State to distribute or sell to any person –

(A) any pesticide that is not registered under section 136a of this title or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this subchapter;

(B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 136a of this title;

(C) any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration under section 136a of this title;

(D) any pesticide which has not been colored or discolored pursuant to the provisions of section 136w(c)(5) of this title;

(E) any pesticide which is adulterated or misbranded; or

(F) any device which is misbranded.

(2) It shall be unlawful for any person –

(A) to detach, alter, deface, or destroy, in whole or in part, any labeling required under this subchapter;

(B) to refuse to –

(i) prepare, maintain, or submit any records required by or under section 136c, 136e, 136f, 136i, or 136q of this title;

(ii) submit any reports required by or under section 136c, 136d, 136e, 136f, 136i, or 136q of this title; or

(iii) allow any entry, inspection, copying of records, or sampling authorized by this subchapter;

(C) to give a guaranty or undertaking provided for in subsection (b) of this section which is false in any particular, except that a person who receives and relies upon a guaranty authorized under subsection (b) of this section may give a guaranty to the same effect, which guaranty shall contain, in addition to the person's own name and address, the name and address of the person residing in the United States from whom the person received the guaranty or undertaking;

(D) to use for the person's own advantage or to reveal, other than to the Administrator, or officials or employees of the Environmental Protection Agency or other Federal executive agencies, or to the courts, or to physicians, pharmacists, and other qualified persons, needing such information for the performance of their duties, in accordance with such directions as the Administrator may prescribe, any information acquired by authority of this subchapter which is confidential under this subchapter;

(E) who is a registrant, wholesaler, dealer, retailer, or other distributor to advertise a product registered under this subchapter for restricted use without giving the classification of the product assigned to it under section 136a of this title;

(F) to distribute or sell, or to make available for use, or to use, any registered pesticide classified for restricted use for some or all purposes other than in accordance with section 136a(d) of this title and any regulations thereunder, except that it shall not be unlawful to sell, under regulations issued by the Administrator, a restricted use pesticide to a person who

is not a certified applicator for application by a certified applicator;

(G) to use any registered pesticide in a manner inconsistent with its labeling;

(H) to use any pesticide which is under an experimental use permit contrary to the provisions of such permit;

(I) to violate any order issued under section 136k of this title;

(J) to violate any suspension order issued under section 136a(c)(2)(B), 136a-1, or 136d of this title;

(K) to violate any cancellation order issued under this subchapter or to fail to submit a notice in accordance with section 136d(g) of this title;

(L) who is a producer to violate any of the provisions of section 136e of this title;

(M) to knowingly falsify all or part of any application for registration, application for experimental use permit, any information submitted to the Administrator pursuant to section 136e of this title, any records required to be maintained pursuant to this subchapter, any report filed under this subchapter, or any information marked as confidential and submitted to the Administrator under any provision of this subchapter;

(N) who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by this subchapter;

(O) to add any substance to, or take any substance from, any pesticide in a manner that may defeat the purpose of this subchapter;

(P) to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasona-

bly foreseeable therefrom, and (ii) freely volunteer to participate in the test;

(Q) to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this subchapter;

(R) to submit to the Administrator data known to be false in support of a registration; or

(S) to violate any regulation issued under section 136a(a) or 136q of this title.

(b) Exemptions

The penalties provided for a violation of paragraph (1) of subsection (a) of this section shall not apply to –

(1) any person who establishes a guaranty signed by, and containing the name and address of, the registrant or person residing in the United States from whom the person purchased or received in good faith the pesticide in the same unbroken package, to the effect that the pesticide was lawfully registered at the time of sale and delivery to the person, and that it complies with the other requirements of this subchapter, and in such case the guarantor shall be subject to the penalties which would otherwise attach to the person holding the guaranty under the provisions of this subchapter;

(2) any carrier while lawfully shipping, transporting, or delivering for shipment any pesticide or device, if such carrier upon request of any officer or employee duly designated by the Administrator shall permit such officer or employee to copy all of its records concerning such pesticide or device;

(3) any public official while engaged in the performance of the official duties of the public official;

(4) any person using or possessing any pesticide as provided by an experimental use permit in effect with respect to such pesticide and such use or possession; or

(5) any person who ships a substance or mixture of substances being put through tests in which the purpose is only to determine its value for pesticide purposes or to determine its toxicity or other properties and from which the user does not expect to receive any benefit in pest control from its use.

7 U.S.C. § 136v. Authority of States

(a) In general

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

(b) Uniformity

Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

(c) Additional uses

(1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this subchapter and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration under section 136a of this title for all purposes of this subchapter, but shall authorize distribution and use only within such State.

(2) A registration issued by a State under this subsection shall not be effective for more than ninety days if disapproved by the Administrator within that period. Prior to disapproval, the Administrator shall, except as provided in paragraph (3) of this subsection, advise the State of the Administrator's intention to disapprove and the reasons therefor, and provide the State time to respond. The Administrator shall not prohibit or disapprove a registration issued by a State under this subsection (A) on the basis of lack of essentiality of a pesticide or (B) except as provided in paragraph (3) of this subsection, if its composition and use patterns are similar to those of a federally registered pesticide.

(3) In no instance may a State issue a registration for a food or feed use unless there exists a tolerance or ex-

emption under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) that permits the residues of the pesticides on the food or feed. If the Administrator determines that a registration issued by a State is inconsistent with the Federal Food, Drug, and Cosmetic Act, or the use of, a pesticide under a registration issued by a State constitutes an imminent hazard, the Administrator may immediately disapprove the registration.

(4) If the Administrator finds, in accordance with standards set forth in regulations issued under section 136w of this title, that a State is not capable of exercising adequate controls to assure that State registration under this section will be in accord with the purposes of this subchapter or has failed to exercise adequate controls, the Administrator may suspend the authority of the State to register pesticides until such time as the Administrator is satisfied that the State can and will exercise adequate controls. Prior to any such suspension, the Administrator shall advise the State of the Administrator's intention to suspend and the reasons therefor and provide the State time to respond.

7 U.S.C. § 136w-1. State primary enforcement responsibility

(a) In general

For the purposes of this subchapter, a State shall have primary enforcement responsibility for pesticide use violations during any period for which the Administrator determines that such State –

(1) has adopted adequate pesticide use laws and regulations, except that the Administrator may not require a State to have pesticide use laws that are more stringent than this subchapter;

(2) has adopted and is implementing adequate procedures for the enforcement of such State laws and regulations; and

(3) will keep such records and make such reports showing compliance with paragraphs (1) and (2) of this subsection as the Administrator may require by regulation.

(b) Special rules

Notwithstanding the provisions of subsection (a) of this section, any State that enters into a cooperative agreement with the Administrator under section 136u of this title for the enforcement of pesticide use restrictions shall have the primary enforcement responsibility for pesticide use violations. Any State that has a plan approved by the Administrator in accordance with the requirements of section 136i of this title that the Administrator determines meets the criteria set out in subsection (a) of this section shall have the primary enforcement responsibility for pesticide use violations. The Administrator shall make such determinations with respect to State plans under section 136i of this title in effect on September 30, 1978, not later than six months after that date.

(c) Administrator

The Administrator shall have primary enforcement responsibility for those States that do not have primary en-

forcement responsibility under this subchapter. Notwithstanding the provisions of section 136(e)(1) of this title, during any period when the Administrator has such enforcement responsibility, section 136f(b) of this title shall apply to the books and records of commercial applicators and to any applicator who holds or applies pesticides, or uses dilutions of pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and section 136g(a) of this title shall apply to the establishment or other place where pesticides or devices are held for application by such persons with respect to pesticides or devices held for such application.

7 U.S.C. § 136w-2. Failure by the State to assure enforcement of State

(a) Referral

Upon receipt of any complaint or other information alleging or indicating a significant violation of the pesticide use provisions of this subchapter, the Administrator shall refer the matter to the appropriate State officials for their investigation of the matter consistent with the requirements of this subchapter. If, within thirty days, the State has not commenced appropriate enforcement action, the Administrator may act upon the complaint or information to the extent authorized under this subchapter.

(b) Notice

Whenever the Administrator determines that a State having primary enforcement responsibility for pesticide use violations is not carrying out (or cannot carry out due to the lack of adequate legal authority) such responsibility, the Administrator shall notify the State. Such notice shall specify those aspects of the administration of the State program that are determined to be inadequate. The State shall have ninety days after receipt of the notice to correct any deficiencies. If after that time the Administrator determines that the State program remains inadequate, the Administrator may rescind, in whole or in part, the State's primary enforcement responsibility for pesticide use violations.

(c) Construction

Neither section 136w-1 of this title nor this section shall limit the authority of the Administrator to enforce this subchapter, where the Administrator determines that emergency conditions exist that require immediate action on the part of the Administrator and the State authority is unwilling or unable adequately to respond to the emergency.

7 U.S.C. § 136w-5. Minimum requirements for training of maintenance applicators and service technicians

Each State may establish minimum requirements for training of maintenance applicators and service technicians. Such training may include instruction in the safe and effective handling and use of pesticides in accordance with the Environmental Protection Agency approved labeling, and instruction in integrated pest management techniques. The authority of the Administrator with respect to minimum requirements for training of maintenance applicators and service technicians shall be limited to ensuring that each State understands the provisions of this section.

7 U.S.C. § 136a. Registration of Pesticides – (1976 ed.)

* * * * *

(c) Procedure for registration

* * * * *

(5) Approval of registration

The Administrator shall register a pesticide if he determines that, when considered with any restrictions imposed under subsection (d) –

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this subchapter;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other.

* * * * *

40 C.F.R. § 152.50. Contents of application.

Each application for registration or amended registration must include the following information, as applicable:

(a) *Application form.* An application form must be completed and submitted to the Agency. Application forms are provided by the Agency, with instructions as to the number of copies required and proper completion.

(b) *Identity of the applicant*–(1) *Name.* The applicant must identify himself. An applicant not residing in the United States must also designate an agent in accordance with paragraph (b)(3) of this section to act on behalf of the applicant on all registration matters.

(2) *Address of record.* The applicant must provide an address in the United States for correspondence purposes. The U.S. address provided will be considered the applicant's address of record, and EPA will send all correspondence concerning the application and any subsequent registration to that address. It is the responsibility of the applicant and any registrant under § 152.122 to ensure that the Agency has a current and accurate address.

(3) *Authorized agent.* An applicant may designate a person residing in the United States to act as his agent. If an applicant wishes to designate an agent, he must send the Agency a letter stating the name and United States address of his agent. The applicant must notify the Agency if he changes his designated agent. This relationship may be terminated at any time by the applicant by notifying the Agency in writing.

(4) *Company number.* If an applicant has been assigned a company number by the Agency, the application must reference that number.

(c) *Summary of the application.* Each application must include a list of the data submitted with the application, together with a brief description of the results of the studies. The list of data submitted may be the same as the list required by § 158.32 of this chapter. The summary must

state that is is [*sic*] releasable to the public after registration in accordance with § 152.119.

(d) *Identity of the product.* The product for which application is being submitted must be identified. The following information is required:

(1) The product name;

(2) The trade name(s) (if different); and

(3) The EPA Registration Number, if currently registered.

(e) *Draft labeling.* Each application for new registration must be accompanied by five legible copies of draft labeling (typescript or mock-up). Each application for amended registration that proposes to make any changes in the product labeling must be accompanied by five legible copies of draft labeling incorporating the proposed labeling changes. If the proposed labeling change affects only a portion of the labeling, such as the use directions, the applicant may submit five copies of that portion of the label which is the subject of the amendment. Upon request, an applicant for amended registration must submit a complete label to consolidate amendments.

(f) *Registration data requirements.* (1) An applicant must submit materials to demonstrate that he has complied with the FIFRA sec. 3(c)(1)(D) and subpart E of this part with respect to satisfaction of data requirements, to enable the Agency to make th determination required by FIFRA sec. 3(c)(5)(B). Required items are described in subpart E of this part.

(2) An applicant must furnish any data specified in part 158 of this chapter which are required by the Agency to determine that the product meets the registration standards of FIFRA sec. 3(c) (5) or (7). Each study must comply with:

(i) Section 158.30 of this chapter, with respect to times for submission;

(ii) Section 158.32 of this chapter, with respect to format of submission;

(iii) Section 158.33 of this chapter, with respect to studies for which a claim of trade secret or confidential business information is made;

(iv) Section 158.34 of this chapter, with respect to flagging for potential adverse effects; and

(v) Section 160.12 of this chapter, if applicable, with respect to a statement of whether studies were conducted in accordance with the Good Laboratory Practices of part 160.

(3) An applicant shall furnish with his application any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on man or the environment, which would be required to be reported under FIFRA sec. 6(a)(2) if the product were registered.

(g) *Certification relating to child-resistant packaging.* If the product meets the criteria for child-resistant packaging, the applicant must submit a certification that the product will be distributed or sold only in child-resistant packaging. Refer to part 157 of this chapter for the criteria and certification requirements.

(h) *Request for classification.* If an applicant wishes to request a classification different from that established by the Agency, he must submit a request for such classification and information supporting the request.

(i) *Statement concerning tolerances.* If the proposed labeling bears instructions for use of the pesticide on food or feed crops, or if the intended use of the pesticide results or may be expected to result, directly or indirectly, in pesticide residues in or on food or feed (including residues of any active ingredient, inert ingredient, metabolite, or degradation product), the applicant must submit a statement indicating whether such residues are authorized by a tolerance, exemption from the requirement of a tolerance, or food additive regulation issued under section 408 or 409 of

the Federal Food, Drug and Cosmetic Act (FFDCA). If such residues have not been authorized, the application must be accompanied by a petition for establishment of appropriate tolerances, exemptions from the requirement of a tolerance, or food additive regulations, in accordance with part 180 of this chapter.

40 C.F.R. § 152.112. Approval of registration under FIFRA sec. 3(c)(5).

EPA will approve an application under the criteria of FIFRA sec. 3(c)(5) only if:

(a) The Agency has determined that the application is complete and is accompanied by all materials required by the Act and this part, including, but not limited to, evidence of compliance with subpart E of this part;

(b) The Agency has reviewed all relevant data in the possession of the Agency (see §§ 152.107 and 152.111);

(c) The Agency has determined that no additional data are necessary to make the determinations required by FIFRA sec. 3(c)(5) with respect to the pesticide product which is the subject of the application;

(d) The Agency has determined that the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data are required to be submitted by part 158 of this chapter for the product;

(e) The Agency has determined that the product will perform its intended function without unreasonable adverse effects on the environment, and that, when used in accordance with widespread and commonly recognized practice, the product will not generally cause unreasonable adverse effects on the environment;

(f) The Agency has determined that the product is not misbranded as that term is defined in FIFRA sec. 2(q) and part 156 of this chapter, and its labeling and packaging comply with the applicable requirements of the Act, this part, and parts 156 and 157 of this chapter;

(g) If the proposed labeling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues (including residues of any active or inert ingredient of the product, or of any metabolite or degradation product thereof) in or on food or animal feed, all necessary tolerances, exemptions from the requirement of a tolerance, and food additive regulations have been issued under FFDCA sec. 408, sec. 409 or both; and

(h) If the product, in addition to being a pesticide, is a drug within the meaning of FFDCA sec. 201(q), the Agency has been notified by the Food and Drug Administration (FDA) that the product complies with any requirements imposed by FDA.

40 C.F.R. § 152.113. Approval of registration under FIFRA sec. 3(c)(7)—Products that do not contain a new active ingredient.

(a) Except as provided in paragraph (b) of this section, the Agency may approve an application for registration or amended registration of a pesticide product, each of whose active ingredients is contained in one or more other registered peticide [*sic*] products, only if the Agency has determined that:

(1) It possesses all data necessary to make the determinations required by FIFRA sec. 3(c)(7)(A) or (B) with respect to the pesticide product which is the subject of the application (including, at a minimum, data needed to characterize any incremental risk that would result from approval of the application);

(2) Approval of the application would not significantly increase the risk of any unreasonable adverse effect on the environment; and

(3) The criteria of § 152.112(a), (d), and (f) through (h) have been satisfied.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide under FIFRA sec. 3(c)(7)(A) unless the Agency has determined that the applicant's product and its proposed use are identical or substantially similar to a currently registered pesticide and use, or that the pesticide and its proposed use differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.

(c) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide product for a new use under FIFRA sec. 3(c)(7)(B) if:

(1) The pesticide is the subject of a special review, based on a use of the product that results in human dietary exposure; and

(2) The proposed new use involves use on a major food or feed crop, or involves use on a minor food or feed crop for which there is available an effective alternative registered pesticide which does not meet the risk criteria associated with human dietary exposure. The determination of available and effective alternatives shall be made with the concurrence of the Secretary of Agriculture.

40 C.F.R. § 156.10. Labeling requirements.

(a) *General*–(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Hazard and precautionary statements as prescribed in subpart D of this part for human and domestic animal hazards and subpart E of this part for environmental hazards.

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such

terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*–(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*–(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to

the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling [*sic*], including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 152.500, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

* * * * *

40 C.F.R. § 156.60. General.

Each product label is required to bear hazard and precautionary statements for humans and domestic animals (if applicable) as prescribed in this subpart. Hazard statements describe the type of hazard that may occur, while precautionary statements will either direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(a) *Location of statements*–(1) *Front panel statements.* The signal word, child hazard warning, and, in certain cases, the first aid statement are required to appear on the front panel of the label, and also in any supplemental labeling intended to accompany the product in distribution or sale.

(2) *Statements elsewhere on label.* Hazard and precautionary statements not required on the front panel may appear on other panels of the label, and may be required also in supplemental labeling. These include, but are not limited to, the human hazard and precautionary statements, domestic animal statements if applicable, a Note to Physician, and physical or chemical hazard statements.

(b) *Placement and prominence*–(1) *Front panel statements.* All required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The table below shows the minimum type size requirements for the front panel warning statements for various front panel sizes.

TYPE SIZES FOR FRONT PANEL WARNING STATEMENTS

Size of Label Front Panel (Square Inches)	Point Size: Signal Word (All Capital Letters)	Point Size: Child Hazard Warning
5 and under	6	6
Over 5 to 10	10	6
Over 10 to 15	12	8
Over 15 to 30	14	10
Over 30	18	12

(2) *Other required statements.* All other hazard and precautionary statements must be at least 6 point type.

40 C.F.R. § 156.62. Toxicity Category.

This section establishes four Toxicity Categories for acute hazards of pesticide products, Category I being the highest toxicity category. Most human hazard, precautionary statements, and human personal protective equipment statements are based upon the Toxicity Category of the pesticide product as sold or distributed. In addition, toxicity categories may be used for regulatory purposes other than labeling, such as classification for restricted use and requirements for child-resistant packaging. In certain cases, statements based upon the Toxicity Category of the product as diluted for use are also permitted. A Toxicity Category is assigned for each of five types of acute exposure, as specified in the table in this paragraph.

ACUTE TOXICITY CATEGORIES FOR PESTICIDE PRODUCTS

Hazard Indicators	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	>50 thru 500 mg/kg	>500 thru 5,000 mg/kg	>5,000 mg/kg
Dermal LD_{50}	Up to and including 200 mg/kg	>200 thru 2000 mg/kg	>2000 thru 20,000 mg/kg	>20,000 mg/kg
Inhalation LC_{50}	Up to and including 0.2 mg/liter	>0.2 thru 2 mg/liter	>2 thru 20 mg/liter	>20 mg/liter
Eye irritation	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin irritation	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

40 C.F.R. § 156.64. Signal word.

(a) *Requirement.* Except as provided in paragraph (a)(4), each pesticide product must bear on the front panel a signal word, reflecting the highest Toxicity Category (Category I is the highest toxicity category) to which the product is assigned by any of the five routes of exposure in § 156.62. The signal word must also appear together with the heading for the human precautionary statement section of the labeling (see § 156.70).

(1) *Toxicity Category I.* Any pesticide product meeting the criteria of Toxicity Category I for any route of exposure must bear on the front panel the signal word "DANGER." In addition, if the product is assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye irritation), the word "Poison" must appear in red on a background of distinctly contrasting color, and the skull and crossbones symbol must appear in immediate proximity to the word "Poison."

(2) *Toxicity Category II.* Any pesticide product meeting the criteria of Toxicity Category II as the highest category by any route of exposure must bear on the front panel the signal word "WARNING."

(3) *Toxicity Category III.* Any pesticide product meeting the criteria of Toxicity Category III as the highest category by any route of exposure must bear on the front panel the signal word "CAUTION."

(4) *Toxicity Category IV.* A pesticide product meeting the criteria of Toxicity Category IV by all routes of exposure is not required to bear a signal word. If a signal word is used, it must be "CAUTION."

(b) *Use of signal words.* In no case may a product:

(1) Bear a signal word reflecting a higher Toxicity Category than indicated by the route of exposure of highest toxicity, unless the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment;

(2) Bear a signal word reflecting a lesser Toxicity Category associated with a diluted product. Although precautionary statements for use dilutions may be included on label, the signal word must reflect the toxicity of the product as distributed or sold; or

(3) Bear different signal words on different parts of the label.

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40 C.F.R. § 156.66. Child hazard warning.

(a) Each pesticide product must bear on the front panel of the label the statement "Keep Out of Reach of Children." That statement, or any alternative statement approved by EPA, must appear on a separate line in close proximity to the signal word, if required. The statement is required on Toxicity Category IV products that do not otherwise require a signal word.

(b) In its discretion, EPA may waive the requirement, or require or permit an alternative child hazard warning, if:

(1) The applicant can demonstrate that the likelihood of exposure of children to the pesticide during distribution, marketing, storage or use is remote (for example, an industrial use product); or

(2) The pesticide is approved for use on children (for example, an insect repellent).

(c) EPA may approve an alternative child hazard warning that more appropriately reflects the nature of the pesticide product to which children may be exposed (for example, an impregnated pet collar). In this case, EPA may also approve placement on other than the front panel.

40 C.F.R. § 156.68. First Aid Statement.

(a) *Product as sold and distributed.* Each product must bear a first aid statement if the product has systemic effects in Category I, II, or III, or skin or eye irritation effects in Category I or II.

(b) *Product as diluted for use.* If the product labeling bears directions for dilution with water prior to use, the label may also include a statement describing how the first aid measures may be modified for the diluted product. Such a statement must reflect the Toxicity Category(ies) of the diluted product, based upon data for the route of exposure (or calculations if appropriate). If the labeling provides for a range of use dilutions, only that use dilution representing the highest concentration allowed by labeling may be used as the basis for a statement pertaining to the diluted product. The statement for a diluted product may not substitute for the statement for the concentrate, but augments the information provided for the concentrate.

(c) *Heading.* The heading of the statement may be "First Aid" or "Statement of Practical Treatment."

(d) *Location of first aid statement.* The first aid statement must appear on the front panel of the label of all products assigned to Toxicity Category I by any route of exposure. Upon review, the Agency may permit reasonable variations in the placement of the first aid statement if a reference such as "See first aid statement on back panel" appears on the front panel. The first aid statement for products assigned to Toxicity Categories II or III may appear on any panel of the label.

40 C.F.R. § 156.70. Precautionary statements for human hazards.

(a) *Requirement.* Human hazard and precautionary statements as required must appear together on the label or labeling under the general heading "Precautionary Statements" and under appropriate subheadings similar to "Humans and Domestic Animals," "Environmental Hazards" (see subpart E of this part) and "Physical or Chemical Hazards." The phrase "and Domestic Animals" may be omitted from the heading if domestic animals will not be exposed to the product.

(b) *Content of statements.* When data or other information show that an acute hazard may exist to humans or domestic animals, the label must bear precautionary statements describing the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or toxic effect or to mitigate the effect. The precautionary paragraph must be immediately preceded by the appropriate signal word.

(c) *Typical precautionary statements.* The table below presents typical hazard and precautionary statements. Specific statements pertaining to the hazards of the product and its uses must be approved by the Agency. With Agency approval, statements may be augmented to reflect the hazards and precautions associated with the product as diluted for use. Refer to § 156.68(b) for requirements for use dilution statements.

TYPICAL HUMAN HAZARD AND PRECAUTIONARY STATEMENTS

Toxicity Category	Systemic effects (oral, dermal, inhalation toxicity)	Irritation effects (skin and eye)	Sensitizer (There are no categories of sensitization.)
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel first aid statement required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Front panel first aid statement required.]	If product is a sensitizer: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
II	May be fatal if swallowed. [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statement required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]	
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes or clothing.	
IV	No precautionary statements required	No precautionary statements required.	

40 C.F.R. § 156.78. Precautionary statements for physical or chemical hazards.

(a) *Requirement.* Warning statements on the flammability or explosive characteristics of the pesticide product are required if a product meets the criteria in this section. Warning statements pertaining to other physical/chemical hazards (e.g., oxidizing potential, conductivity, chemical reactions leading to production of toxic substances) may be required on a case-by-case basis.

(b) *Pressurized products.* The table below sets out the required flammability label statements for pressurized products.

FLAMMABILITY STATEMENTS FOR PRESSURIZED PRODUCTS

–Flash point/flame extension of product	Required labeling statement
–Flash point at or below 20 deg. F OR –Flashback at any valve opening	*Extremely flammable.* Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130 deg. F may cause bursting.

–Flash point <ls-thn-eq> 20 deg. F to 80 deg. F	*Flammable.* Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 deg. F may cause bursting.
OR	
–Flame extension more than 18 in. long at a distance of 6 in from the flame	
All other pressurized products	*Contents under pressure.* Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 deg. F may cause bursting.

(c) *Non-pressurized products.* The table below sets out the required flammability label statements for non-pressurized products.

FLAMMABILITY STATEMENTS FOR NON-PRESSURIZED PRODUCTS

Flash point	Required labeling statement
At or below 20 deg. F	*Extremely flammable.* Keep away from fire, sparks and heated surfaces.
Greater than 20 deg. F to 80 deg. F	*Flammable.* Keep away from heat and open flame.
Greater than 80 deg. F to 150 deg. F	*Combustible.* Do not use or store near heat or open flame.

(d) *Total release fogger products.* (1) A *total release fogger* is defined as a pesticide product in a pressurized container designed to automatically release the total contents in one operation, for the purpose of creating a permeating fog within a confined space to deliver the pesticide throughout the space.

(2) If a pesticide product is a total release fogger containing a propellant with a flash point at or below 20 deg. F, then the following special instructions must be added to the "Physical and Chemical Hazards" warning statement, in addition to any flammability statement required by paragraph (b) of this section:

This product contains a highly flammable ingredient. It may cause a fire or explosion if not used

properly. Follow the Directions for Use on this label very carefully.

(3) A graphic symbol depicting fire, such as illustrated in this paragraph, or an equivalent symbol, must be displayed along with the required language adjoining the "Physical and Chemical Hazards" warning statement. The graphic symbol must be no smaller than twice the size of the first character of the human hazard signal word.

Highly Flammable Ingredient

Ingrediente Altamente Inflamable

40 C.F.R. § 158.540. Plant protection data requirements.

(a) *Table.* Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the plant protection data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns								Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Target area phytotoxicity	(1)	.....	.....	.....	.....	.....	.....	.....	.....	.....	EP	EP	121–1
Nontarget area phytotoxicity.											TGAI	TGAI	122–1
Tier I:													
Seed germination/seedling emergence.	(2)	.....	R	.....	R	.....	.....	R	.....	.....	TGAI	TGAI	122–1
Vegetative vigor	(2)	.....	R	.....	R	.....	.....	R	.....	.....	TGAI	TGAI	122–2
Aquatic plant growth	(2)	.....	R	.....	R	.....	.....	R	.....	.....	TGAI	TGAI	123–1
Tier II:													
Seed germination/seedling emergence.	(3)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TGAI	TGAI	123–1
Vegetative vigor	(3)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TGAI	TGAI	123–2
Aquatic plant growth	(4)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TEP	TEP	124–1
Tier III:													
Terrestrial field	(3)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TEP	TEP	124–2
Aquatic field	(4)	.....	CR	.....	CR	.....	.....	CR	.....	.....			

Key: CR=Conditionally required; TGAI=Technical grade of the active ingredient; EP=End-use product; TEP=Typical end-use product.

(b) NOTES. The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Data are required for Special Review and certain public health situations.

(2) Data are required for pesticides to be used in forests and natural grasslands. For herbicide used in forest site preparation; the aquatic plant growth tests will be required. Data are required to support products to be used in other locations when any of the following conditions are met:

(i) Phytotoxicity problems concerning the product arise and open literature data are not available to address the problems.

(ii) The product may pose hazards to endangered or threatened species.

(iii) Special Review has been initiated on the product.

(3) Required if a 25 percent or greater detrimental effect was found in 1 or more plant species in the corresponding test of the previous tier.

(4) Required if a 50 percent or greater detrimental effect was found on any plant species in the corresponding test of the previous tier.

40 C.F.R. § 158.640. Product performance data requirements.

(a) *Table.* Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the product performance data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Efficacy of antimicrobial agents													
Products for use on hard surfaces.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–2
Products requiring confirmatory data.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–3
Products for use on fabrics and textiles.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–4
Air sanitizers	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–5
Products for control of microbial pests associated with human and animal wastes.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–7
Products for treating water systems.	(1)	.....	.....	[CR]	.....	.....	.....	.....	.....	CR	.....	EP*	91–8
Efficacy of fungicides and nematicides													
Products for control of organisms producing mycotoxins.	(1)	[CR]	.....	[CR]	.....	[CR]	.....	.....	.....	.....	.....	EP*	93–16
Efficacy of Vertebrate Control Agents													
Avian toxicants	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	(R)	.....	EP*	96–5
Avian repellents	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	.....	.....	EP*	96–6
Avian frightening agents ..	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	.....	.....	EP*	96–7
Bat toxicants and repellents.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	(R)	.....	EP*	96–9
Commensal rodenticides ..	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	(R)	TEP	EP*	96–10
Rodenticides on farm and rangelands.	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	.....	.....	EP*	96–12
Rodent fumigants	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	(R)	.....	EP*	96–13
Rodent reproductive inhibitors.	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	(R)	.....	EP*	96–16
Mammalian predacides	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	.....	.....	EP*	96–17

Key: R=Required; CR=Conditionally required; [ ]=Brackets (i.e., [R], [CR]) indicate data requirements that apply to products for which an experimental use permit is being sought; EP=End-use product* (asterisk identifies those data requirements that end-use applicants (i.e., "formulators") must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); MP=Manufacturing use product; TEP=Typical end-use product.

(b) Notes: The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) The Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

(2) [Reserved]

40 C.F.R. § 159.184. Toxic or adverse effect incident reports.

(a) *General.* Information about incidents affecting humans or other non-target organisms must be submitted if the following three conditions are met:

(1) The registrant is aware, or has been informed that a person or non-target organism may have been exposed to a pesticide.

(2) The registrant is aware, or has been informed that the person or non-target organism suffered a toxic or adverse effect, or may suffer a delayed or chronic adverse effect in the future.

(3) The registrant has or could obtain information concerning where the incident occurred, the pesticide or product involved, and the name of a person to contact regarding the incident.

(b) *Exceptions.* Information regarding an incident need not be submitted if any of the following conditions are met:

(1) The registrant is aware of facts which clearly establish that the reported toxic effect, or reported exposure, did not or will not occur.

(2) The registrant has been notified in writing by the Agency that for this incident or category of incidents, and the registrant has not been notified in writing by the Agency that the waiver is rescinded.

(3) It concerns a toxic effect to non-target plants, which were at the use site at the time the pesticide was applied, if the label provides adequate notice of such a risk.

(4) It concerns non-lethal phytotoxicity to the treated crop if the label provides an adequate notice of such a risk.

(5) It concerns a toxic effect to pests not specified on the label, provided that such pests are similar to pests specified on the label.

(6) It concerns minor skin or eye irritation effects warned of on the label of a product which is registered for use in residential use sites, and the effects occurred as a result of use in a residential site.

(c) *Required information on individual incidents.* To the extent that the registrant has any of the information listed in paragraphs (c)(1) through (c)(4) of this section, the registrant must supply the information on each pesticide incident that meets the requirements outlined in paragraph (a) of this section. If the registrant acquires additional information concerning an incident previously reported to the Agency under this part, such information shall be reported if it meets the criteria set forth in paragraph (f) of this section. In the future, the Agency may by notice specify a format for such submissions. The Administrative, Pesticide, Circumstance and Exposure Type(s) of information must be reported for individual incidents, except where the provisions of paragraph (e) of this section allow for aggregated summary forms of reporting, or if EPA in the future grants permission in writing for alternative reporting formats. The registrant must also provide one or more Exposure Type and Severity categories and their designations for each incident as set forth in paragraph (c)(5) of this section, depending on the applicability of the criteria listed below. The criteria listed should be used in assigning a category. For example, an incident which allegedly caused serious but non-fatal effects to human beings and domestic animals might be designated "H-B: D-B." When a single incident involves multiple pesticides, the registrant need only report on their specific product. However, if a single incident involves more than one type of non-target organism–for example, both humans and domestic animals are involved–all appropriate available information dealing with each of the victims must also be reported. The informational items

below are grouped by sections for ease in reporting pesticide incidents.

(1) *Administrative.* Pesticide incident reports must be submitted if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

(i) Name of reporter, address, and telephone number.

(ii) Name, address, and telephone number of contact person (if different than reporter).

(iii) Incident report status (e.g., new or update); if update, include the date of original submission.

(iv) Date registrant became aware of the incident.

(v) Date of incident (if appropriate, list start and end dates).

(vi) Location of incident (city, county and state).

(vii) Is incident part of a larger study.

(viii) Source if different from reporting registrant.

(2) *Pesticide.* Pesticide incident reports must be submitted for each pesticide that may have contributed to the incident, if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

(i) Product name.

(ii) Active ingredient(s).

(iii) EPA Registration Number.

(iv) Diluted for use, or concentrate.

(v) Formulation, if known.

(3) *Circumstance.* Pesticide incident reports must be submitted if the registrant possesses or receives any of the following information, and the incident meets the

minimum requirements set forth in paragraph (a) of this section:

(i) Evidence the label directions were not followed (e.g., yes, no, unknown).

(ii) How exposed (e.g., spill, drift, equipment failure, container failure, mislabeling, runoff, etc.).

(iii) Situation (e.g., household use, mixing/loading, application, reentry, disposal, transportation, other (describe)).

(iv) Use site (e.g., home, yard, commercial turf, agricultural (specify crop), industrial, building/office, school, nursery, greenhouse, pond/lake/stream, well, forest/woods, other.

(v) Applicator certified (yes, no, unknown).

(vi) A brief description of the circumstances of the incident.

(4) *Other incident specific information.* Pesticide incident reports must be submitted if the registrant possesses or receives any of the following information, and the incident meets the minimum requirements set forth in paragraph (a) of this section:

(i) If the incident involves humans:

(A) Route of exposure (skin, eye, respiratory, oral).

(B) List signs/symptoms/adverse effects.

(C) If laboratory tests were performed, list name of test(s) and results.

(D) If available, submit laboratory report(s).

(E) Time between exposure and onset of symptoms.

(F) Was adverse effect the result of suicide/homicide or attempted suicide/homicide.

(G) Type of medical care sought, (e.g., none, Poison Control Center, hospital emergency department, hospital inpatient, private physician, clinic, other).

(H) Demographics (sex, age, occupation).

(I) If female, pregnant?

(J) Exposure data: amount of pesticide; duration of exposure; weight of victim.

(K) Was exposure occupational; days lost due to illness.

(L) Was protective clothing worn (specify).

(ii) If domestic animal:

(A) Type of animal (e.g., livestock, poultry, bird, fish, household pet e.g., dog/cat etc.).

(B) List signs/symptoms/adverse effects.

(C) Breed/species (name and number affected, per adverse effect).

(D) Route of exposure (e.g., skin, eye, respiratory, oral).

(E) Time between exposure and onset of symptoms.

(F) If laboratory test(s) performed, list name of tests and results.

(G) If available, submit laboratory report(s).

(iii) If fish, wildlife, plants or other non-target organisms:

(A) List species affected, and number of individuals per species.

(B) List symptoms or adverse effects.

(C) Magnitude of the effect (e.g., miles of streams, square area of terrestrial habitat).

(D) Pesticide application rate, intended use site (e.g., corn, turf), and method of application.

(E) Description of the habitat and the circumstances under which the incident occurred.

(F) If plant, type of plant life (i.e., crop, forest, orchard, home garden, ornamental, forage).

(G) Formulation of pesticide if not indicated by brand name (granular, flowable).

(H) Distance from treatment site.

(I) If laboratory test(s) performed, list name of test(s) and results.

(J) If available, submit laboratory report(s).

(iv) If surface water:

(A) If raw water samples, water bodies sampled and approximate locations in each water body.

(B) If raw water samples, proximity of sampling locations to drinking water supply intakes and identities of systems supplied.

(C) If finished water samples, water supply systems sampled.

(D) If finished water samples, percent surface water source by specific surface water sources to water supply system(s).

(E) Sample type (grab, composite).

(F) Sampling times/frequency.

(G) Pesticides and degredates analyzed for, the detection limits, and the amount detected.

(H) Method of analysis.

(v) If ground water:

(A) Pesticides and degredates analyzed for, the analytical method used, the detection limits, and the amount detected.

(B) Sample date.

(C) Amount pesticide applied (lbs-ai/acre).

(D) Date of last application.

(E) Depth to water.

(F) Latitude/longitude.

(G) Soil series and texture (sand/silt/clay).

(H) Frequency of applications per year.

(I) Aquifer description (confined/unconfined).

(J) Method of application.

(K) Years pesticide used.

(L) Well use and well identifier.

(M) Screened interval.

(N) Annual cumulative rainfall (inches).

(O) Maximum rainfall and date.

(P) Cumulative irrigation (inches).

(Q) Hydrologic group.

(R) Hydraulic conductivity.

(S) pH.

(T) Organic matter or organic carbon (percent).

(vi) If property damage.

(A) Provide description.

(B) [Reserved]

(5) *Exposure types and severity category designations–* (i) *Humans.* If an effect involves a human, provide the appropriate 2-letter exposure types and severity categories and their designations, based upon the following categories:

(A) H-A: If the person died.

(B) H-B: If the person alleged or exhibited symptoms which may have been life-threatening, or resulted in adverse reproductive effects or in residual disability.

(C) H-C: If the person alleged or exhibited symptoms more pronounced, more prolonged or of a more systemic nature than minor symptoms. Usually some form of treatment of the person would have been Indicated. Symptoms were not life threatening and the person has returned to his/her pre-exposure state of health with no additional residual disability.

(D) H-D: If the person alleged or exhibited some symptoms, but they were minimally traumatic. The symptoms

resolved rapidly and usually involve skin, eye or respiratory irritation.

(E) H-E: If symptoms are unknown, unspecified or are alleged to be of a delayed or chronic nature that may appear in the future.

(ii) *Domestic animals.* If an effect involves a domestic animal, provide the appropriate 2-letter notation based upon the following categories:

(A) D-A: If the domestic animal died or was euthanized.

(B) D-B: If the domestic animal exhibited or was alleged to have exhibited symptoms which may have been life-threatening or resulted in residual disability.

(C) D-C: If the domestic animal exhibited or was alleged to have exhibited symptoms which are more pronounced, more prolonged or of a more systemic nature than minor symptoms. Usually some form of treatment would have been indicated to treat the animal. Symptoms were not life threatening and the animal has returned to its pre-exposure state of health with no additional residual disability.

(D) D-D: If the domestic animal was alleged to have exhibited symptoms, but they were minimally bothersome. The symptoms resolved rapidly and usually involve skin, eye or respirator irritation.

(E) D-E: If symptoms are unknown or not specified.

(iii) *Fish or wildlife.* If an alleged effect involves fish or wildlife, label the incident W-A if any of the following criteria are met, or W-B if none of the criteria are met:

(A) Involves any incident caused by a pesticide currently in Formal Review for ecological concerns.

(B) Fish: Affected 1,000 or more individuals of a schooling species or 50 or more individuals of a non-schooling species.

(C) Birds: Affected 200 or more individuals of a flocking species, or 50 or more individuals of a songbird species, or 5 or more individuals of a predatory species.

(D) Mammals, reptiles, amphibians: Affected 50 or more individuals of a relatively common or herding species or 5 or more individuals of a rare or solitary species.

(E) Involves effects to, or illegal pesticide treatment (misuse) of a substantial tract of habitat (greater than or equal to 10 acres, terrestrial or aquatic).

(F) Involves a major spill or discharge (greater than or equal to 5,000 gallons) of a pesticide.

(G) Involves adverse effects caused by a pesticide, to federally listed endangered or threatened species.

(iv) *Plants.* If an alleged effect involves damage to plants, label the incident P-A if the following criterion is met, or P-B if the criterion is not met:

(A) The effect is alleged to have occurred on more than 45 percent of the acreage exposed to the pesticide.

(B) [Reserved]

(v) *Other non-target organisms.* If an alleged effect involves damage to non-target organisms other than fish, wildlife or plants (for example, beneficial insects), label the incident ONT.

(vi) *Water contamination.* If a pesticide is alleged to have been detected in groundwater, surface water or finished drinking water, label the incident in accordance with the following criteria:

(A) G-A: If the pesticide was detected at levels greater than the maximum contaminant level (MCL) or health advisory level (HAL) or an applicable criterion for ambient water quality.

(B) G-B: If the pesticide was detected at levels greater than 10 percent of the MCL, HAL or a criterion for ambient water quality but does not exceed the MCL or other applicable level.

(C) G-C: If the pesticide was detected at levels less than 10 percent of the MCL, HAL, or other applicable level, or there is no established level of concern.

(vii) *Property damage.* If an incident involves alleged property damage the applicable term(s) shall be included along with any other applicable effect category label; for example, "H-B: property damage." Label the incident in accordance with the following criteria:

(A) PD-A: The product is alleged to have caused damage in a manner that could have caused direct human injury, such as fire or explosion.

(B) PD-B: The product is alleged to have caused damage in excess of $5,000.

(C) PD-C: Any allegation of property damage that does not meet the criteria of paragraphs (c)(5)(vii)(A) or (B) of this section, including cases in which the level of damages is not specified.

(d) *Time requirements for submitting incident information.* Information concerning incidents reportable under this section must be submitted within the time frames listed for different exposure and severity categories, as follows:

(1) For allegations involving human fatality (H-A), registrants must submit the required information, to the extent it is available, no later than 15 days after learning of an allegation.

(2) Information concerning incidents which meet the criteria for the following exposure and severity category labels described in paragraph (c)(5) of this section, reports of detections of pesticides in water, and efficacy failure incidents may be described in § 159.188(a)(1) and (b)(1), may be accumulated for a 30-day period, and submitted to the Agency within 30 days after the end of each 30-day accumulation period for: Humans, H-B, and H-C; Wildlife, W-A; Plants, P-A; Water, G-A; Property Damage, PD-A.

(3) Incidents or reports of detections of pesticides in water meeting all other exposure and severity label categories, information may be accumulated by registrants for 90 days and submitted within 60 days after the end of each 90-day accumulation period.

(e) *Aggregated reports.* For incidents that are reportable under the schedule requirements of paragraph (d)(3) of this section, in lieu of individual reports containing the information listed in paragraphs (c)(1) through (c)(4) of this section, registrants must provide an aggregated report listing:

(1) The time period covered by the report.

(2) For each exposure and severity label category, a count of the number of incidents, listed by product registration number (if known) or active ingredient.

(3) A count of domestic animal incidents in categories, other than D-A or D-B, which can be added together and reported as a single number.

(f) *Reporting additional information.* If, after the submission of an incident report to the Agency, a registrant acquires additional information concerning that incident, the information should be submitted within the same time frame as applied to the original incident report, if any of the following conditions apply:

(1) The information concerns an alleged human fatality (H-A), and the information consists of any of the elements listed in paragraphs (c)(1) through (c)(4) of this section.

(2) The information concerns an incident originally reported as alleging a major human illness or injury (H-B), or fatality to a domestic animal (D-A), or wildlife (W-A), and the additional information consists of pesticide or circumstance information listed in paragraphs (c)(2) or (c)(3) of this section, or is a laboratory report concerning persons or animals involved in the incident.

(3) The information concerns any incident not originally reported with one of the exposure and severity labels H-A,

or H-B for human incidents, or at the "A" level of severity for any other exposure or incident type, and the new information would result in labeling the incident H-A or H-B for a human incident, or at the "A" level of severity for any other exposure or incident type listed in paragraph (c)(5) of this section.

40 C.F.R. § 162.153. State registration procedures.

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(e) *Labeling requirements.* (1) Prior to issuing any registration, the State shall review the proposed labeling submitted with the application to determine compliance with this paragraph. In addition, the State shall review a copy of the final printed labeling as soon as practical after a registration is issued in order to verify compliance with this paragraph.

(2) For a new product, the State must, as a condition of the registration, require that the product be accompanied from the time it enters the stream of commerce by labeling meeting all applicable criteria of § 156.10 of this chapter. New product labeling must all contain:

(i) A statement identifying the State where registration is to be valid.

(ii) The special local need registration number assigned by the State.

(3) Except as provided in paragraph (e)(4) of this section, as a condition for a registration of an additional use of a federally registered product, the State must require that at the time of sale to users, labeling from the federally registered product be accompanied by supplemental labeling which contains:

(i) A statement identifying the State where registration is valid.

(ii) Directions for use to meet the special local need which satisfy the criteria of § 156.10(i) of this chapter.

(iii) The trade name of the product.

(iv) The name and address of the section 24(c) registrant.

(v) The EPA registration number of the federally registered product.

(vi) The special local need registration number assigned by the State.

(vii) A statement prohibiting use of the product in a manner inconsistent with all applicable directions, restrictions, and precautions found in the labeling of the federally registered product and accompanying supplemental labeling.

(4) When a federally registered product is already in the stream of commerce at the time the State issues a registration for an additional use of that product, the State must ensure that supplemental labeling for the additional use, meeting the criteria of paragraph (e)(3) of this section, is made available to purchasers and users of the product within 45 days of the date on which the State approves the final printed supplemental labeling.

(5) If a State classifies for restricted use a product or use registered by the State, which is not required to be so classified by paragraph (g) of this section, then the State may require supplemental labeling for the product or use containing additional appropriate precautions, and a statement that the product or use is for restricted use within that State.

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